EXHIBIT BB

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
Master File No. 2:12-MD-02327

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM, PRODUCTS LIABILITY LITIGATION

MDL No. 2327

This Document Relates to:

Carolyn Lewis, Et Al v. Ethicon, Inc. Case No. 2:12-CV-04301

IN THE DISTRICT COURT, 95th JUDICIAL DISTRICT DALLAS COUNTY, TEXAS

Linda Batiste,

Plaintiff,

v. Cause No.
John Robert McNabb, M.D., DC-12-14350
Johnson & Johnson and Ethicon, Inc.,
Defendants.

DEPOSITION OF HOWARD C. JORDI, Ph.D.

Wednesday, October 30th, 2013

9:05 a.m.

Held At:

Jordi Lab 200 Gilbert Street Mansfield, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RPR, CLR, CSR #149108

Golkow Technologies, Inc. - 1.877.370.DEPS

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1	APPEARANCES:	1	INDEX
2	FOR THE PLAINTIFFS:	2	EXAMINATION PAGE
3	BY: BENJAMIN H. ANDERSON, ESQ.	3	HOWARD C. JORDI, Ph.D.
4	ANDERSON LAW OFFICES, LLC	4	BY MR. THOMAS 5
5	1360 West 9th Street, Suite 215	5	BY MR. ANDERSON 286
6	Cleveland, Ohio 44113	6	EXHIBITS 260
7	216-589-0256	7	NO. DESCRIPTION PAGE
8	ben@andersonlawoffices.com	8	1 Rule 26 Expert Report of Howard
9	-and-	9	
10	BY: DANIEL J. THORNBURGH, ESQ.	10	Jordi, PhD in the Carolyn Lewis
11	AYLSTOCK, WITKIN, KREIS & OVERHOLTZ PLLC	11	case 6 2 Document titled Final Report, Linda
12	17 East Main Street, Suite 200	12	1 ,
13		13	Batiste
	Pensacola, Florida 32502		3 De Tayrac and Letouzey article
14	850-202-1010	14	titled "Basic science and clinical
15	dthornburgh@awkolaw.com	15	aspects of mesh infection in pelvic
16	EOD THE DEFENDANTS ETHICON INC I JOHNSON 8	16	floor reconstructive surgery 54
17	FOR THE DEFENDANTS ETHICON, INC., and JOHNSON &	17	4 Liebert, et al study titled
18	JOHNSON:	18	Subcutaneous Implants of
19	BY: DAVID B. THOMAS, ESQ.	19	Polypropylene Filaments
20	THOMAS COMBS & SPANN, PLLC	20	5 Group of invoices from Jordi Labs183
21	300 Summers Street, Suite 1380	21	6 10/30/13 Final Report for Linda
22	Charleston, West Virginia 25301	22	Batiste209
23	304-414-1807	23	7 Group of films267
24	dthomas@tcspllc.com	24	
25		25	_
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1	APPEARANCES VIA SPEAKERPHONE	1	P R O C E E D I N G S
2	FOR THE PLAINTIFF CAROLYN LEWIS:	2	
3	BY: CALLE M. MENDENHALL, ESQ.	3	HOWARD C. JORDI, Ph.D.,
4	FREESE & GOSS PLLC	4	having been first duly identified and sworn, was
5	Regions Harbert Plaza 1901	5	examined and testified as follows:
6	6th Avenue North	6	DIRECT EXAMINATION
7	Birmingham, Alabama 35203	7	BY MR. THOMAS:
8	205-871-4144	8	Q. Good morning, Dr. Jordi.
9	calle@freeseandgoss.com	9	A. Good morning.
10		10	Q. I introduced myself to you before the
11	FOR DEFENDANT DR. JOHN McNABB in the Batiste	11	deposition. My name is David Thomas, and I
12	case:	12	represent the Defendants in the case. And I'm
13	BY: PHILIPA M. REMINGTON, ESQ. (AM)	13	going to take your deposition in two matters,
14	CHARLES A. ESTEE, ESQ. (PM)	14	the Carolyn Lewis matter and the Batiste case
15	THIEBAUD, REMINGTON, THORNTON, BAILEY, LLF	15	from Texas.
16	1445 Ross Avenue, Suite 4800	16	You understand that?
17	Dallas, Texas 75202	17	A. I do.
18	214-954-2210	18	Q. We're here in your offices in
19	premington@trtblaw.com	19	Massachusetts?
20		20	A. Yes, we are.
21		21	Q. And is Massachusetts your home?
22		22	A. It is.
23		23	Q. Okay. Would you state your full name
24		24	for the record, please?
25		25	A. Howard Craig Jordi.

2 (Pages 2 to 5)

1	Page 6		Page 8
	Q. And you're a Dr. Jordi, correct?	1	final, rather than looking at each and every
2	A. That's correct.	2	page, he's trying to do the best he can in the
3	Q. A Ph.D doctor?	3	interest of time.
4	A. A Ph.D doctor.	4	MR. THOMAS: It's 847 pages, and I'll
5	Q. Not a medical doctor?	5	represent to you that we copied it as best we
6	A. Not a medical doctor.	6	could and produced it for him, and I'm just
7	Q. And in what area is your Ph.D?	7	trying to get him to identify it as best he can.
8	A. Biochemistry.	8	MR. ANDERSON: So stipulated.
9	Q. What is a biochemist?	9	MR. THOMAS: The Batiste report is
10	A. A biochemist is one who studies the	10	some 240 pages, and I don't expect him to go
11	reactions of chemicals in the body.	11	through every page, unless he wants to. But
12	Q. Okay. Dr. Jordi, I've been provided	12	I'll represent that's a copy of what was
13	two reports in this case. I'm going to mark as	13	supplied to me.
14	deposition Exhibit Number 1 what's been provided	14	MR. ANDERSON: Right.
15	to me as your Rule 26 expert report of Howard	15	MR. THOMAS: I'm trying to just get it
16	Jordi, Ph.D in the Carolyn Lewis case.	16	identified as best we can.
17	A. Okay.	17	MR. ANDERSON: Right. I'm just saying
18	(Whereupon, Jordi Exhibit Number 1,	18	he's leafing through it to do the best he can
19	Rule 26 Expert Report of Howard Jordi,	19	without taking every page and looking at it in
20	PhD in the Carolyn Lewis case, was	20	detail.
21	marked for identification.)	21	A. It appears to be complete.
22	MR. THOMAS: And I'm going to mark as	22	BY MR. THOMAS:
23	Exhibit Number 2 what's been provided to me as a	23	Q. Okay. Dr. Jordi, how do you charge
24	document titled Final Report for Linda Batiste.	24	for your time?
25		25	A. I bill hourly.
	Page 7		Page 9
1	(Whereupon, Jordi Exhibit Number 2,	1	O A = 1 1 - 4 1 1 1 4 - 9
1		1	Q. And what is your hourly rate?
2	Document titled Final Report, Linda	2	A. 350 an hour.
	Batiste, was marked for		A. 350 an hour.Q. Is your hourly rate the same for
2 3 4	Batiste, was marked for identification.)	2 3 4	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do?
2 3 4 5	Batiste, was marked for identification.) BY MR. THOMAS:	2 3 4 5	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes.
2 3 4 5 6	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did.	2 3 4 5 6	 A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount
2 3 4 5 6 7	Batiste, was marked for identification.) BY MR. THOMAS:	2 3 4 5 6 7	 A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the
2 3 4 5 6 7 8	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to	2 3 4 5 6 7 8	 A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report?
2 3 4 5 6 7 8 9	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem	2 3 4 5 6 7 8	 A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the
2 3 4 5 6 7 8 9	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough.	2 3 4 5 6 7 8 9	 A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that.
2 3 4 5 6 7 8 9 10	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it	2 3 4 5 6 7 8 9 10	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today?
2 3 4 5 6 7 8 9 10 11	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be.	2 3 4 5 6 7 8 9 10 11 12	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do.
2 3 4 5 6 7 8 9 10 11 12 13	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all	2 3 4 5 6 7 8 9 10 11 12 13	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS:
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case. Can you review those quickly, or as	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same. MR. THOMAS: Okay. Ben, we'll come
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case. Can you review those quickly, or as much time as you need, and confirm for me that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same. MR. THOMAS: Okay. Ben, we'll come back to that in a few minutes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case. Can you review those quickly, or as much time as you need, and confirm for me that those are complete copies of your expert reports	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same. MR. THOMAS: Okay. Ben, we'll come back to that in a few minutes. MR. ANDERSON: Sure.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case. Can you review those quickly, or as much time as you need, and confirm for me that those are complete copies of your expert reports in the case?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same. MR. THOMAS: Okay. Ben, we'll come back to that in a few minutes. MR. ANDERSON: Sure. BY MR. THOMAS:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case. Can you review those quickly, or as much time as you need, and confirm for me that those are complete copies of your expert reports in the case? (Witness reviewing documents.)	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same. MR. THOMAS: Okay. Ben, we'll come back to that in a few minutes. MR. ANDERSON: Sure. BY MR. THOMAS: Q. Those billing records are readily
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case. Can you review those quickly, or as much time as you need, and confirm for me that those are complete copies of your expert reports in the case? (Witness reviewing documents.) MR. ANDERSON: I'd just like for the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same. MR. THOMAS: Okay. Ben, we'll come back to that in a few minutes. MR. ANDERSON: Sure. BY MR. THOMAS: Q. Those billing records are readily available, and you can determine how much it
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case. Can you review those quickly, or as much time as you need, and confirm for me that those are complete copies of your expert reports in the case? (Witness reviewing documents.) MR. ANDERSON: I'd just like for the record to reflect that it's an almost 800 page	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same. MR. THOMAS: Okay. Ben, we'll come back to that in a few minutes. MR. ANDERSON: Sure. BY MR. THOMAS: Q. Those billing records are readily available, and you can determine how much it cost you to produce Exhibit 1, the report in
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Batiste, was marked for identification.) BY MR. THOMAS: Q. Okay. And let me tell you what I did. Those are double-sided copies because I didn't care to A. I was going to say it didn't seem thick enough. Q. It's half as thick as you expected it to be. A. Yes. Q. Because I didn't care to carry all those papers with me. These are the documents that were provided by counsel in the case. Can you review those quickly, or as much time as you need, and confirm for me that those are complete copies of your expert reports in the case? (Witness reviewing documents.) MR. ANDERSON: I'd just like for the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. 350 an hour. Q. Is your hourly rate the same for whatever work that you do? A. Yes. Q. Have you calculated the total amount dollars that you've billed for Exhibit 1, the Lewis report? A. We'd have to look at the receipts, the billings for that. Q. Do you have those with you today? A. I believe we do. MR. ANDERSON: Yes. BY MR. THOMAS: Q. And the same for the Batiste matter? A. Same. MR. THOMAS: Okay. Ben, we'll come back to that in a few minutes. MR. ANDERSON: Sure. BY MR. THOMAS: Q. Those billing records are readily available, and you can determine how much it

3 (Pages 6 to 9)

Page 10 Page 12 1 1 A. I don't know if this has been billed Q. All right. Do you understand that 2 2 yet, but this one should be. I think we bill there are different products that are at issue 3 3 in the Lewis case and the Batiste case? monthly, so it hasn't gone out yet. 4 4 Q. When you say "this one," you're MR. ANDERSON: Objection. 5 5 referring to Exhibit 2, which is Linda Batiste? Go ahead. 6 6 A. The samples that I received I just A. Yes. sir. 7 7 received and ran by identification numbers Q. Okay. And do you have records that 8 you'd be able to get sometime during the day so 8 without regards to -- certainly the pristine 9 9 that I can tell how much time you have into it materials were identified. 10 that hasn't been billed so I know how much cost 10 BY MR. THOMAS: Q. Okay. Do you have any knowledge --11 there was for the Linda Batiste report? 11 12 12 MR. ANDERSON: I might be able to help what I'm trying to get at, Doctor, is, I'll 13 13 you. In response to your notice of subpoena, represent to you, my understanding anyway, is 14 14 the Carolyn Lewis case involves a product known the 21 categories, we did our best to try to 15 respond to those, the ones that we thought he 15 as a TVT Classic or a TVT Retropubic, and the 16 16 could respond to, and as part of that we tried Batiste case, Exhibit Number 2, I understand, 17 to get as up to date a billing as we could for 17 involves a product known as a TVT Obturator or you, and that would include as much of Batiste 18 18 TVT-O. 19 as possible, at least up until last week. 19 Do you know that? 20 MR. THOMAS: Okay. 20 A. No. That wasn't represented to us, as 21 21 MR. ANDERSON: So that's -- we've far as I'm concerned. 22 Q. As far as you're concerned --22 tried. And I think that you'll be able to look 2.3 23 at it, and from the dates be able to tell A. It's an explant. 24 whether or not it includes anything this week or 24 Q. Okay. In the work that you did in 25 25 these matters, does it concern you at all Page 11 Page 13 1 MR. THOMAS: Perfect. 1 whether this is a TVT Classic or a TVT Obturator 2 BY MR. THOMAS: 2 or a TVT Retropubic or TVT-O? 3 Q. For the Carolyn Lewis case, your final 3 A. No. They're all polypropylene, and in 4 report in Exhibit Number 1, is that a complete 4 that sense, for that reason, no. 5 copy of the report of the opinions that you 5 Q. Is it fair to understand, Doctor -intend to give in the Carolyn Lewis case? 6 б just trying to do something to make this easier, 7 7 A. It is. believe it or not -- is it fair to understand, 8 8 Q. Do you have any intention of doing any Doctor, that the work that you did in analyzing 9 additional work prior to testifying in trial in 9 the mesh explants and the mesh controls that's 10 this case in connection with new opinions for 10 represented in Exhibit Number 1 and Exhibit 11 the Carolyn Lewis case? 11 Number 2 do not depend on the type of product MR. ANDERSON: I'm just going to 12 that you were analyzing? 12 13 object, because as counsel knows, we have a 13 MR. ANDERSON: Objection. 14 right to do rebuttal reports in this case, so he 14 Go ahead. 15 may not even understand that. And so with that 15 A. As a polymer chemist and having 16 caveat, that as he sits here today. 16 studied polypropylene, among others, for my A. To my knowledge, this is complete, and 17 lifetime of work, basically polypropylene is 17 18 this is what I will be using. 18 polypropylene is polypropylene, so it's going 19 to -- if it's polypropylene it's going to have 19 BY MR. THOMAS: 20 Q. Same question with respect to Linda 20 the characteristic reactions of polypropylene. 21 21 Batiste, Exhibit Number 2; does Exhibit Number 2 BY MR. THOMAS: 22 represent a complete report of the opinions that 22 Q. Did the work that you did for Exhibit 23 you're prepared to give in the Linda Batiste 23 Number 1 differ from the work that you did in 24 case? 24 Exhibit Number 2 because of the name of the 25 product that was analyzed in each case? 25 A. Yes.

4 (Pages 10 to 13)

Page 14 Page 16 A. Did not. 1 BY MR. THOMAS: 1 2 2 Q. Absolutely. I'm sorry. 3 3 A. Do I need to reference this one, MR. ANDERSON: Go ahead. That's fine. 4 4 BY MR. THOMAS: because it's not marked? 5 Q. And what were you trying to do when 5 MR. ANDERSON: You can look at 6 6 you -- what were you asked to do in Exhibit anything. 7 7 Number 1? A. It's this. I just want to make sure I 8 A. We were asked to compare pristine mesh 8 have all of the techniques referenced here that 9 9 samples and explant samples and determine I did. 10 whether or not there were differences; and if 10 We did optical microscopy as well to 11 11 there were, what they were. see if there were any obvious differences, and 12 Q. What did you understand to be the 12 to just look at the shape of the fibers. 13 13 differences that you were looking for? GPC. I think we got them all. A. I wasn't told to look for any specific 14 14 MR. ANDERSON: Did you say GPC? 15 differences. I was told to look for 15 A. Gel permeation chromatography. GPC 16 16 differences, if there were any. for molecular weight. 17 Q. And how did you set out to determine 17 BY MR. THOMAS: 18 whether there were differences between the 18 Q. How did you determine what tests to 19 explants and the pristine samples that you'd 19 conduct on the mesh that you analyzed in Exhibit 20 received? 20 Number 1? 21 21 A. Given the knowledge that it was A. I've analyzed these kinds of materials 22 22 polypropylene, classic tests that we would since 1980. In this particular business we 23 23 typically run on any polypropylene would be built -- I founded this company, and so it's 24 molecular weight, to see if it degraded in terms 24 just years and years of experience. 25 of its molecular weight. 25 Polypropylene has to be stabilized because it's Page 17 Page 15 1 We would look for additive content. a reactive polymer. That information goes back 2 because that stabilizes polypropylene. 2 at least to the '60s. So you've got to look for 3 How am I doing speed-wise? 3 the antioxidants, the presence or lack thereof. 4 So we did additives analysis. 4 GPC is to determine the molecular weight, as I 5 We would do DSC to look for 5 said. DSC is to determine the melt point and 6 б the FLP at melt, which correlates with percent crystallinity. 7 7 We did SEM to look for cracks. crystallinity. SEM is a means of looking at the 8 8 We did SEM-EDX to look for elemental physical shape of the fibers. So these are just 9 composition. Specifically we were looking for 9 standard techniques that we used. So we chose 10 differing oxygen levels which would indicate and 10 standard techniques that I would use for any 11 correlate with oxidation, if present. 11 such type of analysis. We did FTIR analysis to look for 12 Q. Type of such analysis, what do you 12 13 presence of carbonyls. And we specifically 13 mean by that? 14 there wanted to find out whether the flaking 14 A. Well, in our company we analyze any 15 material, once we saw it from the SEM, was 15 kind of polymer. So we analyze polystyrene one polypropylene or not, what was the composition, 16 day, we analyze contact lens materials another 16 17 chemical composition of the flakes that were day, we analyze polypropylene, some of which 17 18 coming off the polypropylene fibers. I'm trying 18 have been implanted in the human bodies, hips 19 19 to think. and so on on another day. You could really call 20 So we also ran PYMS. That's another 20 us a materials lab. 21 21 technique to look for additives, presence of Q. Okay. What I'm trying to understand 22 additives. 22 is when you got this request from Mr. Anderson 23 I need to --23 and his associates and they asked you to analyze 24 MR. ANDERSON: Do you want to 24 this polypropylene material both as an explant 25 25 reference your report? and as a pristine sample, did you go to the

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Page 18 Page 20 shelf and pull off a list and say "I'm going to 1 1 Engineers, yes. 2 2 do this list of tests"? Q. And for what purpose do you cite 3 3 A. No, because I already knew it from Dr. Müller, is that the additives analysis? 4 4 experience. A. There would be additives analysis, 5 5 stabilization of various polymers, polypropylene Q. Okay. 6 6 A. We would do this type of work for any being one of them. 7 7 Q. Are there any other texts or client. 8 Q. So the tests that you identified for 8 authorities upon which you rely to identify the 9 9 purposes of your report in both Exhibits 1 and tests that you need to contact on the explants 10 Exhibits 2 are based upon your training, 10 and the pristine samples? 11 11 A. To identify the tests needed? education, and experience, as opposed to any 12 12 reference guide that you may have looked to to Q. Yes. 13 13 determine what tests you may have run, is that A. Well, reading 400 pages of literature, 14 14 fair? and part of it is just the body of knowledge 15 A. Well, I have reference guides. I mean 15 that you get from reading all of the literature. 16 16 I have books. I do continue to -- reading is an Everyone in the last -- starting back -- going 17 ongoing learning technique I continue to use, 17 back to the '60s has used these techniques. 18 and always will. 18 Q. Okay. Q. Sure. 19 19 A. Some of them, of course, are more 20 A. But no, I wouldn't need to read those 20 modern today, obviously, than they were in the 21 21 books to pop up with the techniques because '60s. Today we have available FTIR microscopy, 22 22 they're standard in the industry. which we can look at a tiny sample. We didn't 23 23 Q. Is there a place where I could go have that available them. LCMS didn't exist in 24 to -- if they came to me and said "Mr. Thomas, I 24 the '70s and '60s, does now. So some of these 25 want to have these polypropylene tests run on 25 techniques have come along in terms of Page 19 Page 21 1 this pristine control and this explant, what 1 development that are available today that tests should I run?" Is there a place where you 2 2 weren't available prior times. But, again, 3 could direct me to figure out what would be the 3 today it's just -- every paper you read they 4 appropriate tests to identify the differences 4 use -- we use some of the same methods. LCMS is 5 between the explants and the controls? 5 one of the bright and shining stars today that's 6 б MR. ANDERSON: Objection as to form. come -- really come on strong in the last 7 7 20 years, 10 to 20 years. Go ahead. 8 8 A. There's probably chapters like that, Q. Real simple question, hopefully it's a 9 books on chemical analysis that would suggest 9 simple answer. 10 methodologies. 10 Can you direct me to any authority, 11 Generally you have a body of 11 textbook, article, whatever you use in your experience developed over many years, you 12 business and in your expertise, that would 12 13 just -- at this point in my life, I would know 13 identify the tests that you would do to detect 14 14 that I need to look up additives, for example, the differences between an explanted piece of 15 but then I would go to the Dr. Müller text which 15 polypropylene mesh and a pristine control of the 16 is in our reference list to look up how 16 mesh? 17 17 additives were used in various materials, and I MR. ANDERSON: Objection. Asked and answered. 18 would look under polypropylene, and I would find 18 19 what additives are typically used for 19 Go ahead. 20 polypropylene specifically. So I'd know what to 20 A. I don't know of any such text that 21 21 look for. just has a single page where it lists -- if I want to know about thermal methods, I'd go to 22 BY MR. THOMAS: 22 23 Q. And you're referring to a text cited 23 Edith Turi that I've cited. If I want to know 24 in your report by a Dr. Müller? 24 about GPC, I'd go to Modern GPC chromatography 25 25 A. Dr. Müller, Society of Plastics text that I have. I have all these individual.

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Page 22 Page 24 1 1 And if you go to -- Odiam, for that you analyzed? 2 2 example, would be another one that's a common A. Well, SEM would be certainly a major 3 3 text that's used in polymer chemistry training methodology. It gives you a visual observation 4 4 sessions at like University of Connecticut where of -- I'd have to add SEM to the term 5 my son got his doctorate, he took -- he used 5 degradation, but it's a visual measurement as 6 6 that text. In that text you will see a chapter opposed to a chemical measurement. 7 7 on DSC, you will see a chapter on GPC, you'll Q. Okay. 8 see a chapter on IR, you'll see all these 8 A. But it makes it very obvious if 9 9 various techniques. something is degrading or not. 10 But it might not include every one I 10 Q. Other than degradation as you have 11 11 just defined it, and the SEM visual observations used. I don't know that I can say -- I don't 12 think I can say there's any one book that has 12 that you've just described, did you look for any 13 13 every single method in it necessarily. other differences between the polypropylene in 14 14 Q. Is it fair to understand, Doctor, that the control samples and the polypropylene in the 15 each of these tests that you ran were designed 15 explanted mesh? 16 16 to detect any differences between the control A. I'm not sure I understand how to 17 sample of the mesh and the explant sample of the 17 answer that question. We looked for differences 18 18 mesh? which included all the tests that we've 19 A. That was the entire intent of the 19 discussed; the molecular weight analysis, the 20 proceeding, as far as I understood it. It was 20 additives. 21 21 just to look for differences, if there were any. Q. Don't all -- my question is; all the 22 22 Q. Okay. What is degradation? tests that you ran are designed to determine the 23 23 A. Well, degradation would be the loss of extent to which the polypropylene degraded, is 24 functionalness of, in this case, a polymer for 24 that fair? 25 its intended purpose. 25 A. Or could degrade. For example, if Page 23 Page 25 1 Q. Okay. 1 additives, antioxidants come out of the 2 A. That could include things like 2 polypropylene, initially it may not be degraded, 3 oxidation, or environmental stress cracking. It 3 so I can't say that's degradation in and of 4 could include mechanical degradation. For 4 itself. 5 example, when products are -- waste materials in 5 However, once the antioxidants are out б the manufacturing process are re-used, they make б of the polypropylene, it is now vulnerable to 7 7 pellets out of the re-used material and they oxidation. So it's a very valid technique in 8 8 call it regrind, and each regrind cycle tends to predicting the longevity, the functionalness of 9 degrade the polymer, so that's a type of 9 the product. 10 degradation. 10 Q. Okay. So can we define it this way; 11 Q. Other than degradation as you've just 11 that the tests that you ran, as you've just 12 identified them, were designed to determine the 12 defined it, did you look for any other 13 differences in the polymer in the control sample 13 extent to which the polypropylene in the 14 as compared to the polymer in the explant? 14 explanted mesh had degraded as compared to the 15 A. Can I have the question repeated, 15 control, and the extent to which it might please? degrade in the future? 16 16 17 A. I like that better. 17 Q. Sure. 18 Other than the degradation as you've 18 Yes. just defined it, did you look for any 19 19 Q. Okay. And you named three kinds, you 20 differences -- I'm going to change the question 20 named oxidation, environmental stress cracking, 21 because I'm going to use a different term. 21 and mechanical degradation, is that fair? 22 Other than degradation as you've just 22 A. That's correct. 23 defined it, did you look for any differences in 23 Q. Your paper, your report discusses a 24 the polypropylene in the control sample as 24 bunch of other types of degradation. Can we 25 25 compared to the polypropylene in the explant focus on these three as being those types of

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degradation at which you looked for purposes of both Lewis and Badiste? A. Well, right. You would have you could have UV light degradation, but that wouldn't be applicable to this case. Q. The answer to my question, can we limit our questions in this case to oxidation, and the SEM visual analysis of these meshes? Q. The answer to my question, can we limit our questions in this case to oxidation, and the SEM visual analysis of these meshes? Maybe it's not. Page 12, you talk about sample preparation. Go ahead. A. Well, I want to be able to include FIR. for example. Page 27 Page 27 Page 27 A. Show oxidation. 10 the		Page 26		Page 28
both Lewis and Batiste? A. Well, right. You would have you could have UV light degradation, but that wouldn't be applicable to this case. Q. The answer to my question, can we limit our questions in this case to oxidation, environmental strose reacking, mechanical degradation, and the SEM visual analysis of these meshes? MR. ANDERSON: Objection. G. Oba abead. A. Well, I want to be able to include FIR, for example. BY MR. THOMAS: Q. Where did you go to determine how to prepare your sample for preparation for your analysis? Did you consult any text, or are there standard methodologies that you use to prepare your samples for the testing that you're good shape there. Q. Right. A. Well, I want to be able to include FIR, for example. BY MR. THOMAS: Q. Where did you go to determine how to prepare your samples for preparation for your analysis? Did you consult any text, or are there standard methodologies that you use to prepare your samples for the testing that you're good shape there. Q. Right. A. Hink were in pretty good shape there. Q. Okay. All I'm trying to do is make this shorter instead of longer. And so I'm not trying to trick you at all, believe it or not. A. Mr. Anderson asked you to do. And you determined on your own what battery of tests to conduct in order to evaluate the control samples and the mesh explant samples, how did you determine how to prepare those samples for the test shat you conducted? A. That's correct. Q. When you received the samples that you were to compare, I'm talking about the control samples and the mesh explant samples, how did you determine how to prepare those samples for the tests that you conducted? A. That's correct. Q. When you received the samples that you were to compare, I'm talking about the control or the mesh? MR. ANDERSON: Objection. Do you want to talk about the control or the mesh? MR. ANDERSON: Objection. Do you want to talk about the control or the mesh? MR. THOMAS: MR. THOMAS: MR. ANDERSON: Solay. MR. THOMAS: A. Well, with the cont	1	degradation at which you looked for purposes of	1	the
A. Well, right. You would have — you doubt have UV light degradation, but that wouldn't be applicable to this case. Q. The answer to my question, can we limit our questions in this case to oxidation, environmental stress cracking, mechanical degradation, and the SEM visual analysis of these meshes? MR. ANDERSON: Objection. Go ahead. A. Well, I want to be able to include FITIR, for example. MR. ANDERSON: Objection. Go ahead. A. Well, I want to be able to include FITIR, for example. MR. ANDERSON: Objection. Go ahead. A. Well, I want to be able to include FITIR, for example. MR. ANDERSON: Objection. A. So the control samples were received for preparation. My where it is every simple, I think. My where it is gought is not Page 12, you talk about sample preparation. Do you consult any text, or are there standard methodologies that you use to prepare your samples for the testing that you are to there. Well, I want to be able to include MR. ANDERSON: Objection. Page 27 A. So the control samples were received for MR HOMAS: Q. Where did you go to determine how to prepare your samples for preparation for your analysis. Play ou consult any text, or are there standard methodologies that you use to prepare your samples for the testing that you re yoing to do? MR. ANDERSON: Objection. Page 27 A. Mr. Anderson. Q. And you've already described what Mr. Anderson asked you to do. And you determined on your own what battery of tests to conduct in order to evaluate the control mesh against the explanted mesh, correct? A. That's correct. Q. When you received the samples that you were to compare, I'm talking about the control samples and the mesh explant samples, how did you determine how to prepare those samples for testing? MR. ANDERSON: Objection. Do you want to talk about the control of the mesh? MR. ANDERSON: Objection. Do you want to talk about the control of the mesh? MR. ANDERSON: Objection. Do you want to talk about the control of the mesh? MR. ANDERSON: Objection. MR. ANDERSON: Objection				
december of the applicable to this case. 6 Q. The answer to my question, can we limit our questions in this case to oxidation, environmental stress cracking, mechanical degradation, and the SEM visual analysis of these meshes? 11 degradation, and the SEM visual analysis of these meshes? 12 MR. ANDERSON: Objection. 13 A. Well, I want to be able to include 14 FIIR, for example. 15 BY MR. THOMAS: 16 Q. Why question is pretty simple, I think. Maybe it's not. Page 12, you talk about sample preparation. 17 A. Show oxidation. 18 Q. But FTIR is designed to discuss— 18 A. Mr. Anderson. 19 A. I think we're in pretty good shape 19 there. 20 there. 21 Q. Okay. All I'm trying to do is make this shorter instead of longer. And so I'm not trying to trick you at all, believe it or not. 22 T. Q. Okay. All I'm trying to do is make this shorter instead of longer. And so I'm not trying to trick you at all, believe it or not. 22 T. Q. Okay. All I'm trying to do is make there. 23 T. A. Mr. Anderson. 24 All right. So you to coexided—first of all, who hired you in this case? 25 T. A. Mr. Anderson. 26 Q. Mand you've already described what against the explanted mesh, correct? 27 A. That's correct. 28 Q. When you received the samples that you were to compare, I'm talking about the control samples and the mesh explant samples, how did you determine how to prepare those samples for terms. 29 MR. ANDERSON: Objection. 20 Do you want to talk about the control or the mesh? 20 MR. ANDERSON: Oslay. 31 MR. ANDERSON: Oslay. 42 MR. THOMAS: 43 MR. ANDERSON: Oslay. 44 MR. ANDERSON: Oslay. 45 MR. THOMAS: 46 Or Hem are did you go to determine how to prepare there standard methodologies that you use to prepare your samples for the esting that you are with an optical microscope, and we have scalpels, and aseptic tweezers, that's just our SOP. 46 A. Mr. Anderson asked you to do. And you determine on your own what battery of tests to conduct this analysis in writing? 48 A. Mr. Anderson asked you to do. And you determine how to prepare the season proc				
5 Wouldn't be applicable to this case. 6 Q. The answer to my question, can we limit our questions in this case to oxidation, and the SEM visual analysis of degradation, and the SEM visual analysis of these meshes? 10 these meshes? 11 MR. ANDERSON: Objection. 12 Go ahead. 13 A. Well, I want to be able to include FIR, for example. 14 FIR, for example. 15 BY MR. THOMAS: 16 Q. But FIR is designed to discuss - 17 A. Show oxidation. 18 Q. Right. 19 A. I think we're in pretty good shape there. 19 Q. Okay. All I'm trying to do is make this shorter instead of longer. And so I'm not trying to trick you at all, believe it or not. 21 All right. So you received first of all, who hired you in this case? 22 this modern and the standard perature of the testing that you determined on your own what battery of tests to conduct in order to evaluate the control mesh against the explanted mesh, correct? 2 A. That's correct. 3 Q. When you received the samples that you were to compare, I'm talking about the control samples and the mesh explant samples, how did so samples and the mesh explant samples, how did you determine how to prepare those samples for testing? 3 MR. ANDERSON: Objection. 4 Do you want to talk about the control or mesh? 4 MR. THOMAS: Both. 5 MR. THOMAS: Both. 6 My there did you go to determine how to prepare these standard area analysis? Did you go usual tany text, or are there standard methodologies that you use to prepare your sample for preparation for your analysis; Did you consult any text, or are there standard methodologies that you use to prepare your samples for the testing that you're pare with an optical microscope, and we have scalpels, and aseptic tweezers, and disposable scalpels, and aseptic tweezers, that's just our SOP. 20 And you've already described what Mr. Anderson asked you to do. And you determine how to prepare those samples for the tests that you conducted? 3 preparation. 5 MR. ANDERSON: Objection. 5 Q. When you received he samples that you in the scale of the preparation. 5 Q. When did yo				
6 Q. My question is pretty simple, I think. 8 environmental stress cracking, mechanical 9 degradation, and the SEM visual analysis of 10 these meshes? 11 MR. ANDERSON: Objection. 12 Go ahead. 13 A. Well, I want to be able to include 14 FIR, for example. 15 BY MR. THOMAS: 16 Q. Right. 17 A. Show oxidation. Q. Right. 19 A. I think we're in pretty good shape 19 there. 20 there. 21 Q. Okay. All I'm trying to do is make 22 this shorter instead of longer. And so I'm not 23 trying to trick you at all, believe it or not. 24 All right. Soy our received—first 25 of all, who hired you in this case? 28 Page 27 29 A. Mr. Anderson. Q. And you've already described what 30 Mr. Anderson asked you to do. And you 40 determined on your own what battery of tests to 50 conduct in order to evaluate the control 10 samples and the mesh explant samples, thow 11 you determine how to prepare these samples for 12 testing? MR. ANDERSON: Objection. 13 MR. ANDERSON: Objection. 14 Do you want to talk about the control 15 or the mesh? 16 MR. ANDERSON: Objection. 17 MR. ANDERSON: Objection. 18 MR. ANDERSON: Objection. 19 MR. ANDERSON: Okay. 19 MR. THOMAS: Buth. 10 MR. ANDERSON: Okay. 10 MR. ANDERSON: Okay. 11 MR. ANDERSON: Okay. 12 MR. ANDERSON: Okay. 13 MR. ANDERSON: Okay. 14 MR. THOMAS: Buth. 15 MR. ANDERSON: Okay. 16 MR. ANDERSON: Okay. 17 MR. ANDERSON: Okay. 18 MR. THOMAS: Buth. 18 MR. THOMAS: I'll do it first. 19 MR. THOMAS: I'll do it first. 20 Q. How did you determine how to prepare 21 your control samples for testing? 22 A. Well, with the control samples we had more material, boxes came in, and we had pictures in here of the process. I think that 24 more material, boxes came in, and we had pictures in here of the process. I think that 25 material may be it send in you determine how to prepare 26 material may be it send in you determine how to prepare 27 material methods require disposate the testing that you determine how to prepare 28 material methods require and disposable scalpels, and aseptic tweezers, that's just our scalpels, and a				
Timit our questions in this case to oxidation, environmental stress cracking, mechanical degradation, and the SEM visual analysis of these meshes?				
8 environmental stress cracking, mechanical 10 degradation, and the SEM visual analysis of 11 these meshes? 12 Go ahead. 13 A. Well, I want to be able to include 14 FIJR, for example. 15 BY MR. THOMAS: 16 Q. But FIJR is designed to discuss— 17 A. Show oxidation. 18 Q. Right. 19 A. I think we're in pretty good shape 19 A. I think we're in pretty good shape 19 A. I think we're in pretty good shape 19 A. I think we're in pretty good shape 10 there. 11 A. Mr. Anderson and a think of all right. 12 A. Mr. Anderson asked you to do. And you 19 A. Mr. Anderson asked you to do. And you 19 A. Mr. Anderson asked you to do. And you 19 A. Mr. Anderson asked you to do. And you 19 A. That's correct. 20 A. That's correct. 21 A. That's correct. 22 A. That's correct. 23 That's correct. 24 A. That's correct. 25 MR. ANDERSON: Objection. 26 MR. ANDERSON: Objection. 27 MR. ANDERSON: Objection. 28 MR. ANDERSON: Objection. 29 MR. ANDERSON: He just said 20 The mesh? 20 MR. THOMAS: Buth. 21 Do you want to talk about the control 21 or the mesh? 22 MR. THOMAS: Buth. 23 MR. ANDERSON: Okay. 24 MR. THOMAS: Buth. 25 MR. THOMAS: Buth. 26 MR. ANDERSON: Okay. 27 MR. ANDERSON: Okay. 28 MR. THOMAS: Buth. 29 MR. THOMAS: Buth. 20 Q. How did you determine how to prepare 20 A. Well with the control samples for testing? 21 MR. ANDERSON: Okay. 22 MR. THOMAS: Buth. 23 MR. THOMAS: Buth. 24 MR. THOMAS: Buth. 25 MR. THOMAS: Buth. 26 MR. THOMAS: Buth. 27 MR. ANDERSON: Okay. 28 MR. THOMAS: Buth. 29 MR. THOMAS: Buth. 30 MR. ANDERSON: Okay. 31 MR. ANDERSON: Okay. 32 MR. THOMAS: Buth. 33 MR. THOMAS: Buth. 34 MR. THOMAS: Buth. 35 MR. THOMAS: Buth. 36 MR. THOMAS: Buth. 37 MR. ANDERSON: Okay. 38 MR. THOMAS: Buth. 39 A. Right. 4 A. Mell, in the case with polyour osus that you bree as tandard area with an optical microscope, and we have scalpels, and we have tweezers, that's just our scalpels, and we have tweeters have a with				
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Page 30 Page 32 1 1 the samples are passed to each specific analyst. Q. Continuing on Page 12, you discuss 2 2 But as far as -- I have a whole pile of SOPs taking a sample of each control material, about 3 3 over here for you for each of those methods. 100 milligrams, placing it in formalin, 4 4 Q. Okay. Probably what I'll do during 90 milliliters and heat it at 60 degrees 5 5 lunch. centigrade for 48 hours. "In my experience, 6 6 MR. ANDERSON: That's why the question this temperature would be expected to provide an 7 7 is a little tough. When you're saying sample accelerated rate of aging and is consistent with other published methods for this purpose." 8 preparation, there's all these different tests 8 9 9 that were done, so the question embodies a lot What does that mean? 10 of things. I didn't want to keep objecting. 10 A. Well, the samples have been sitting in 11 11 MR. THOMAS: I appreciate that. storage at Steelgate for some time, we don't 12 BY MR. THOMAS: 12 know how long exactly, at least I don't. The --13 13 Q. On Page 12 of your report, under so if it had been in Steelgate for a month, and "Sample Preparation," you discuss a "Control Experiment." It says "The control samples were 14 14 we put it in formalin here for a day, it 15 15 wouldn't be equivalent treatment. So to get it 16 16 also used as part of a control experiment as close to being equivalent treatment as we 17 designed to provide an indication as to the 17 could we tried to -- in effect, we tried to 18 18 effects of formalin storage." accelerate any potential aging by running it at 19 Why did you conduct a control 19 -- like doing the storage at 60 for 48 hours, so 20 experiment designed to provide indication as to 20 it would be more like the treatment that it 21 21 the effects of formalin storage? would have received for, say, a month, or 22 22 whatever the time was, from Steelgate. A. The samples received from Steelgate 23 23 came informally, they were shipped to us that Q. You cite to two references for this 24 way, and we wanted to know what effect formalin 24 process, it's the ASTM Standard D3045, and the 25 would have on pristine polypropylene, or not, as 25 Inoue paper, 1961, the Journal of Polymer Page 31 Page 33 1 the case might be, so we wanted to rule out any 1 Science on Page 13 of your report. 2 potential oxidation caused by formalin of the 2 A. Correct. 3 explants that were slipped to us, so we tried 3 Q. Do those two references support using 4 the controls the same way. 4 60 degrees centigrade for 48 hours to replicate 5 Q. What is it about formalin that caused 5 the aging process of polymer controls? 6 б you to be concerned about potential oxidation to A. Well, various methods are used. But 7 7 in general the principle -- definitely supports the mesh? 8 8 A. Nothing specifically. It's just good the principle. Various temperatures and times 9 lab practice to make sure that you treat -- if I 9 are given for various polymers, and so this was 10 want to compare a pristine mesh with an explant, 10 just trying to follow the principles. Q. What age of explants in formalin does 11 I want the pristine mesh that I'm calling a 11 12 60 degrees centigrade for 48 hours for the 12 standard to be treated identically, period, as 13 much as I possibly can control it, to the 13 controls represent? explant material. Since the explant was in 14 14 A. As to age at room temperature, 15 formalin, it's wise to put your control in 15 specifically I don't know. 16 formalin so they're treated identically. So any 16 Q. Okay. Why did you choose 60 degrees 17 differences then seen can't be attributed to the centigrade for 48 hours? 17

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A. Because that was consistent with these

two references that would be recommended. If it

doesn't show -- the point being if it doesn't

Q. Okay. So is it fair to understand

that the 60 degrees centigrade for 48 hours is

not designed to reflect any specific time that

time, it likely isn't going to react.

show up in this temperature in this amount of

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formalin treatment, if there was any. I didn't

know there was or not. But that is just good

chemical reaction issues associated between

chemical properties of polypropylene?

Q. As a biochemist, are you aware of any

formalin and polypropylene that may affect the

lab practice to me.

A. In general, no.

Page 34 Page 36 1 1 the explants may have been in formalin, but to preserve their explant samples? 2 2 designed to determine if the formalin would have A. Because it's a preservative. 3 3 Q. When you say "preservative," does that any degradation on the controls at any time? 4 4 A. It was determined -- it was an attempt have a chemical meaning to you? 5 5 to determine if formalin would react with A. It has a more of a biological meaning. 6 6 The formaldehyde preserves tissue and preserves polypropylene. 7 7 anything from anything that's in it, from Q. And what did your experiment conclude? 8 A. All the tests, SEM, and all the rest 8 bacterial growth which would degrade biological 9 9 of the tests, FTIR, showed no change. materials. 10 Q. So is it your conclusion from that 10 Q. Okay. You said two things there, as I 11 analysis that formalin has no chemical impact on heard it. I'm going to do the second one first. 11 12 polypropylene? 12 You said it prevents bacterial growth. Tell me what that means, please. 13 13 A. That's correct. 14 14 A. Well, in tissue, if you have -- by Q. Have you done any research to 15 determine the extent to which formalin has any 15 itself it just will pick up bacteria from flies 16 16 impact on polypropylene? landing on it or just from the air, and then it 17 A. No, I have not. 17 will begin to degrade. Q. Okay. So it would be the influence of 18 18 Q. Formalin is --19 A. Other than the test. 19 the outside bacteria growing on the explant that 20 MR. ANDERSON: What did you say? 20 may have an impact on the chemical composition 21 21 A. Other than this test, of course. of the explant, is that fair? 22 22 BY MR. THOMAS: A. That's one piece of it. But another 23 23 Q. Formalin is a mixture of formaldehyde? piece would be if there were bacteria in the 24 A. Yes. 24 tissue -- for example, if there were an 25 Q. Did you do any research to determine 25 infection in the mesh that was taken out, that Page 37 Page 35 1 the extent to which formaldehyde had any would be bacteria, it could continue to grow as 2 chemical impact on polypropylene? 2 well. I can't sort that out. 3 A. Well, in all the published literature, 3 Q. Okay. The other thing you said, as I 4 I looked at all these articles, I read over 400 4 wrote it down, is that formaldehyde preserves 5 pages, various authors determined -- did various 5 tissue. 6 б studies of explanted materials. Everybody in How does formaldehyde preserve tissue? 7 7 the world, as far as I can see, treats their A. It makes for an aseptic environment. 8 8 samples with -- or essentially everyone uses Bacteria can't grow in it, so hence, there's no 9 formaldehyde as a preservative. If you didn't 9 degradation. 10 do that, you would allow for potential bacterial 10 Q. So it's actually consistent with your second point, and that is it arrests the 11 growth and things like that that might degrade 11 12 development of bacteria to prevent any 12 the polymer. 13 Q. My question was different. 13 degradation of the explant, is that correct? 14 Dr. Jordi, did you do any research to 14 A. That's the intent, yes. 15 determine the extent to which formaldehyde can 15 Q. Are you aware of any chemical reaction have a chemical reaction with and degrade 16 that formaldehyde has with proteins that may be 16 17 17 polypropylene? on explants? A. No. 18 18 A. Absolutely. Formaldehyde is an 19 aldehyde, and it will react with any things like 19 MR. ANDERSON: Objection. 20 BY MR. THOMAS: 20 amines. It can react with any other reactor 21 21 Q. A minute ago you said that everyone group that typical aldehydes with react with. uses formaldehyde to preserve their -- what? 22 22 Q. As a part of your analysis in this 23 A. Their explant samples. 23 case, did you study the impact of formaldehydes 24 Q. Okay. And do you have an 24 on any proteins that may be on explanted meshes? 25 25 understanding of why everyone uses formaldehyde A. No, we did not.

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Page 38 Page 40 Q. Did you consider that issue at all in 1 1 I'll explore each of those in a little more 2 2 your analysis? detail rather than going through the report and 3 A. No. 3 finding each one. 4 4 Q. Doctor, you identified three types of Does that make sense? 5 5 degradation which you analyzed in connection MR. ANDERSON: Your question was all 6 6 the evidence of oxidation, so that made it a with your work in Exhibits 1 and 2, and one was 7 7 oxidation, the second was environmental stress little tougher. 8 cracking, and the third was mechanical 8 MR. THOMAS: I'm sorry. I'm not very 9 9 smart sometimes. degradation, correct? 10 A. Yes. 10 MR. ANDERSON: It's not about smart. Q. What evidence in your testing for 11 11 I think he wants a more general 12 Exhibit 1 for the Lewis case did you find 12 question to begin with, and then he'll go into 13 oxidation? 13 the --14 14 A. For that we're going to have to go to A. Well, SEM-EDX, for sample, showed --15 15 SEM-EDX showed increased oxygen levels in the the report. 16 16 cracked region that we just talked about. MR. ANDERSON: Anything you need to 17 reference in your report you can reference it. 17 BY MR. THOMAS: A. Well, the first thing we saw -- that 18 18 Q. Okay. 19 we looked at was SEM, and then that's coupled 19 A. And you don't want to talk about 20 with SEM-EDX, so we'll look at a couple SEM 20 figures at this point? 21 21 charts first. Q. No. 22 A. Just concepts? 22 Page 26 shows a typical explanted 2.3 23 sample. Figure 16 shows transverse cracks of Q. Exactly. Thank you. 24 surface polypropylene. 24 A. All right. I'll try to do my best, 25 BY MR. THOMAS: 25 sir. Page 39 Page 41 Q. You're doing fine. 1 Q. Let me stop you there, if I can. Are 1 2 you finished? 2 A. DSC showed a decrease in the heat 3 A. Yes. 3 effusion, and a decrease in the melt temperature versus non-cracked material. That correlates 4 Q. I don't want to interrupt you. 4 5 The surface cracking that you just 5 with environmental stress cracking, because the described on the record, this is your visual 6 б Delta H at melt correlates with the amount or 7 7 observation that you talked about before that the percentage of crystallinity, and hence the 8 8 you believe is evidence of oxidation, is that percentage of amorphous materials, which allows 9 correct? 9 things like cholesterol and cholesterol esters 10 A. This is visual evidence of either 10 and fatty acids to get into the cracking. FTIR microscopy dearly showed -- by 11 oxidation or environmental stress cracking, or 11 12 using the microscopic version of FTIR, coupled, 12 both, and by itself it can't tell you the 13 difference. 13 we were able to actually take IRs of each flaked 14 14 Q. Got you. piece, and this flaked piece clearly showed 15 But it's strictly visual? 15 protein and polypropylene. And since the A. This one is visual, yes, sir. 16 polypropylene bands are weaker than carbonyl 16 Figure 22 is another good example. 17 bands, they're alkyl, absorbance bands versus 17 18 Q. What page are we on, please? 18 carbonyl, this chart that I'm looking at of this A. 29. Flaking polypropylene pieces. 19 19 particular flaked piece would be estimated to be 20 Q. Now, you can do whatever you want to, 20 about 75 percent or so polypropylene, maybe 21 21 I'm looking for -- perhaps it would be easier 25 percent protein. this way. You don't have to do all the figures Q. Okay. 22 22 23 that talk about visual observations. What I'm 23 A. Because they're both there. 24 looking for specifically is each type of 24 Q. And just generally for now, we'll go 25 specifically to those issues later. 25 oxidation that you found in your report, then

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	Page 42		Page 44
1	A. Okay. The molecular weight averages	1	BY MR. THOMAS:
2	that were determined showed basically no	2	Q. Yes.
3	difference between cracked samples and pristine.	3	A. Generally the percentage of oxygen in
4	Q. Help me there.	4	oxidized polypropylene, at least initially, is
5	A. And formalin treated.	5	in the low percent range. So it doesn't take
6	Q. That is not evidence of oxidation, is	6	very much increase in oxygen in polypropylene to
7	it, the fact that they're the same?	7	cause embrittlement, rigidity, and those kind of
8	A. Are you asking only for evidence of	8	effects. Those are caused by presence of
9	oxidation?	9	ketones and aldehydes as the oxidation goes on,
10	Q. Correct.	10	carboxylic acids if it goes far enough.
11	A. Okay. We'll skip that.	11	Q. Doctor, my question is a little more
12	Q. Just so we're clear	12	specific than that.
13	A. Right.	13	Did you attempt to measure the extent
14	Q the molecular weight analysis you	14	of oxidation in any of the mesh implants
15	did is not consistent with oxidation?	15	quantitatively?
16	A. In and of, and by itself it is not.	16	A. It would be relative quantitation,
17	Q. Thank you.	17	comparing control versus explant.
18	A. PYMS showed generally a lack of or	18	Q. Did you express any measurement of
19	very great minimization of both Santonox R and	19	oxidation in the explants compared to the
20	lauryl thiodipropionate.	20	controls in your report?
21	Q. Okay. And those are antioxidants?	21	A. I'm sorry, can you repeat the
22	A. Those are the two antioxidants that	22	question?
23	are in the formulation, in the recipe from	23	Q. Did you set forth any opinion as to
24	Ethicon.	24	the extent of oxidation from the explants
25	Q. Is it fair to understand, though, that	25	measured quantitatively in your report?
	Page 43		Page 45
1	the PYMS analysis does not show oxidation, but	1	MR. ANDERSON: Objection.
2	is part of your earlier analysis about potential	2	Go ahead.
3	future oxidation?	3	A. Again, it was a relative thing, so I
4	A. That's correct, it is. Okay.	4	don't know that I can say. It would be
5	Q. So the PYMS analysis itself does not	5	quantitative.
6	show oxidation of the polypropylene in the	6	But, for example, pristine
7	explants?	7	polypropylene didn't show any carbonyl to 1760,
8	A. It shows vulnerability to oxidation is	8	1740 that we could see. But the explants did.
9	what it shows.	9	BY MR. THOMAS:
10	Q. It does not show any oxidation in the	10	Q. Did you attempt to measure in that
11	explants?	11	context the extent to which the carbonyl issue
12	A. In and of itself, no.	12	had any impact on the ability of the
13	Q. Thank you.	13	polypropylene to function for its intended
14	Have we covered the basics on the	14	purpose?
15	oxidation?	15	A. All oxidation is bad. It's a relative
16	A. I think so.	16	determination. So you would hope there wouldn't
17	Q. For those places where you found	17	be any carbonyl observed, is what you would look
18	evidence of oxidation, as you've just described	18	for if the material is good.
19	and as reflected in your report, were you ever	19	Your question, I'm sorry.
20	able to measure the extent of antioxidation of	20	Q. Might have been a bad question. Let
21	the explants that you analyzed?	21	me see if I can do it again.
22	MR. ANDERSON: Objection.	22	In your analysis of oxidation, did you
23	Go ahead.	23	ever measure the extent to which the
24 25	A. Are you talking about quantitative	24	polypropylene in the explanted meshes was
	numbers now?	25	degraded in a quantitative way?

12 (Pages 42 to 45)

Page 46 Page 48 1 A. In a relative quantitative way is all 1 they were handed to the appropriate technician 2 2 we did. to do the sampling that's described in the 3 Q. And tell me what that means. 3 photograph. They're removed -- now you're 4 4 A. Well, that means if I have a peak for talking about the actual --5 carbonyl, I have -- like if I had no peak in the 5 Q. Explants, correct. 6 6 pristine and I have a peak, a measurable peak in A. -- explant. 7 7 the explant, then I can say with certainty that Received tissue bundles. 8 the explanted material is more oxidized than the 8 Q. You're on page? 9 9 pristine. A. Now I'm on 16. 10 10 Q. Thank you. Q. Are we talking about oxidation to the 11 11 A. And little pieces were cut off with extent that it compromises the ability of the 12 polymer to function for its intended purpose? 12 disposable scalpel. And the picture on the 13 13 A. The only way I know to answer this is right -- I'll wait for you to get there if you 14 in science we would pool multiple methods. I 14 want. 15 have to look at the SEM photographs and look at 15 Q. I'm fine. Go ahead. 16 16 the carbonyl levels and try to correlate the A. Little pieces were cut off, and that's 17 carbonyl with the degree of damage actually 17 what was then repackaged in formalin for 18 observed physically in the SEM. So that's the 18 shipment for SEM. 19 kind of thing what I mean by "relative." 19 Q. Okay. As we look on Page 16, there 20 Q. Do you have an opinion as you sit here 20 are four photos there in Figure 2. The top left 21 21 today, based on your training, education, photo in Figure 2 is the way that you received 22 22 experience, and review of the materials in this the sample? 2.3 23 case, of the extent to which the polypropylene A. Yes. 24 in the mesh explants oxidized in the context of 24 Q. Dumped out of container, is that fair? 25 the loss of functionalness for its intended 25 MR. ANDERSON: Objection. Page 47 Page 49 A. Yes. 1 purpose? 1 2 2 BY MR. THOMAS: A. Yes, I do. 3 Q. Okay. What is that opinion? 3 Q. I'm sorry, I'm trying to be casual. 4 A. The material appears degraded, some of 4 Excuse me. That was a bad question. 5 it severely degraded. There's a range from 5 Mr. Anderson is exactly right. 6 б sample to sample. And in two cases of 23 Dr. Jordi, is it fair to understand 7 7 samples that we ran, we didn't see any damage. that the top left on Figure 16 reflects the 8 8 91 percent of the time we did. samples as received before you did anything to 9 Q. Are you talking now about your visual 9 them? observations through the scanning electron 10 A. That's correct. 10 11 microscopy? 11 Q. And how did you separate the mesh in A. Yes, correlating that, of course, with 12 the lower left-hand corner in Figure 2 from the 12 13 the carbonyls. 13 tissue that appears on the lower right-hand 14 14 Q. I'm talking about the analysis that we corner of Figure 2? 15 -- strike that. Let me come back to that. 15 A. We utilized forceps to pull the tissue Doctor, let's go back to your sample 16 off of the sample. As you can see, in the left 16 preparation. That's what happens when I find 17 bottom picture there are little bits of tissue 17 18 rabbit holes. 18 left. 19 19 What steps did you take to prepare the Q. Who did that? Did you do that? 20 explants that you received for analysis? 20 A. Adi Kulcarni. Took about an hour a 21 21 MR. ANDERSON: Objection. sample. 22 Go ahead. 22 Q. And did you use forceps in each hand, 23 A. Well, the samples were received at our 23 is that how you do that? Or how do you do that? 24 receiving area, and then they were -- the boxes 24 A. He just -- he has to hold it, he has 25 25 were photographed, and they were removed, and to hold it while he pulls tissue off.

13 (Pages 46 to 49)

	Page 50		Page 52
1	Q. Hold it in his hand?	1	Dr. Kulcarni about the methodology to separate
2	A. No. With forceps.	2	the tissue from the mesh?
3	Q. So you've got the forceps?	3	A. No. It appeared very gentle, as good
4	A. Two, yes.	4	as we could possibly do.
5	Q. Two forceps.	5	Q. Okay. Other than separating the
6	Is there a Jordi standard operating	6	tissue from the mesh, as you've just described
7	procedure about how to remove tissue from mesh?	7	in Figure 2 on Page 16 of your report, which is
8	A. No.	8	Exhibit Number 1, were there any efforts made to
9	Q. How was it determined how to remove	9	otherwise treat the mesh prior to testing?
10	the tissue from the mesh?	10	A. No.
11	A. Well, the technique was to remove the	11	Q. For the tissue sample that appears in
12	tissue touching the as little as possible the	12	the upper left of Figure 2 on Page 16, was there
13	mesh itself so that you wouldn't cause any	13	any discussion about trying to clean that
14	damage to it.	14	sample?
15	Q. Did you instruct this technician is	15	A. Well, that's what we've just been
16	that the right word?	16	discussing. This was how it was cleaned, it was
17	A. No. He's a Ph.D.	17	done with forceps.
18	Q. Did you instruct what's his name	18	Q. Okay. At any time was there a
19	again? I'm sorry.	19	discussion with Dr. Kulcarni about cleaning the
20	A. Adi Kulcarni.	20	mesh that was removed from the tissue to remove
21	Q. Did you instruct Dr. Kulcarni on the	21	proteinaceous material from the mesh?
22	method to separate the mesh from this tissue?	22	A. No.
23	A. No, I did not.	23	Q. Is it fair to understand, Dr. Jordi,
24	Q. Do you know what procedure he followed	24	that the mesh that appears on Page 16 in the
25	or what strike that.	25	lower left-hand corner is mesh that has been
	Page 51		Page 53
1	Do you know what methodology he	1	separated from the tissue without further
_	Calle and the surface of the test and the C		1
2	followed in order to protect the integrity of	2	cleaning?
3	the mesh and the tissue as he separated the two?	2 3	cleaning? A. That's correct.
3 4	the mesh and the tissue as he separated the two? A. Well, it was set out, I believe, on a	3 4	cleaning? A. That's correct. Q. Did you ever consider cleaning the
3 4 5	A. Well, it was set out, I believe, on a piece of tissue so it wouldn't be contaminated	3 4 5	cleaning? A. That's correct. Q. Did you ever consider cleaning the mesh that was separated from the tissue in order
3 4 5 6	the mesh and the tissue as he separated the two? A. Well, it was set out, I believe, on a piece of tissue so it wouldn't be contaminated with anything in the area. It was a clean work	3 4 5 6	cleaning? A. That's correct. Q. Did you ever consider cleaning the mesh that was separated from the tissue in order to strike that.
3 4 5 6 7	the mesh and the tissue as he separated the two? A. Well, it was set out, I believe, on a piece of tissue so it wouldn't be contaminated with anything in the area. It was a clean work area to begin with, and used aseptic forceps.	3 4 5 6 7	cleaning? A. That's correct. Q. Did you ever consider cleaning the mesh that was separated from the tissue in order to strike that. Did you ever consider cleaning the
3 4 5 6 7 8	the mesh and the tissue as he separated the two? A. Well, it was set out, I believe, on a piece of tissue so it wouldn't be contaminated with anything in the area. It was a clean work area to begin with, and used aseptic forceps. Q. Is there a standard methodology, of	3 4 5 6 7 8	cleaning? A. That's correct. Q. Did you ever consider cleaning the mesh that was separated from the tissue in order to strike that. Did you ever consider cleaning the mesh that was separated from the tissue prior to
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3 4 5 6 7 8 9 10 11 12	the mesh and the tissue as he separated the two? A. Well, it was set out, I believe, on a piece of tissue so it wouldn't be contaminated with anything in the area. It was a clean work area to begin with, and used aseptic forceps. Q. Is there a standard methodology, of which you're aware, that tells Dr. Kulcarni how to properly separate the mesh from the tissue? A. I don't think so. I don't think one exists. I've never seen one.	3 4 5 6 7 8 9 10 11 12	cleaning? A. That's correct. Q. Did you ever consider cleaning the mesh that was separated from the tissue in order to strike that. Did you ever consider cleaning the mesh that was separated from the tissue prior to conducting your tests that you did in Exhibit 1? A. At the time this work was done, no. Q. Before you did your work in Exhibits 1 and 2, did you do any research into analysis by
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the mesh and the tissue as he separated the two? A. Well, it was set out, I believe, on a piece of tissue so it wouldn't be contaminated with anything in the area. It was a clean work area to begin with, and used aseptic forceps. Q. Is there a standard methodology, of which you're aware, that tells Dr. Kulcarni how to properly separate the mesh from the tissue? A. I don't think so. I don't think one exists. I've never seen one. Q. Did you discuss with Dr. Kulcarni how to appropriately separate the mesh and tissue? A. Did I discuss with him how to do it? Q. Yes. A. We discussed yes, we had discussions. But, you know, he is a very, very careful worker. Q. What was the purpose of your discussions with Dr. Kulcarni about how to separate the tissue from the mesh?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	cleaning? A. That's correct. Q. Did you ever consider cleaning the mesh that was separated from the tissue in order to strike that. Did you ever consider cleaning the mesh that was separated from the tissue prior to conducting your tests that you did in Exhibit 1? A. At the time this work was done, no. Q. Before you did your work in Exhibits 1 and 2, did you do any research into analysis by other scientists in the methodology for testing explanted meshes? A. I did. Q. And what research did you do? A. I read a number of articles, Clavé and others. Q. You read Costello? A. Costello. Q. Did you read de Tayrac? A. Yes.

14 (Pages 50 to 53)

	Page 54		Page 56
1	(Whereupon, Jordi Exhibit Number 3,	1	in the lower left-hand corner you have the mesh
2	de Tayrac and Letouzey article titled	2	separated from the tissue, correct?
3	"Basic science and clinical aspects of	3	A. Correct.
4	mesh infection in pelvic floor	4	Q. And you understand when the mesh is in
5	reconstructive surgery, was marked for	5	the body was in the body it was surrounded by
6	identification.)	6	materials in the body?
7	A. Are you going to de Tayrac?	7	A. That's right.
8	BY MR. THOMAS:	8	Q. Including proteins?
9	Q. Yes.	9	A. And those materials are shown in the
10		10	bottom right picture. That is the material
11	Let me show you what I marked as	11	• •
	deposition Exhibit Number 3. You have Exhibit	12	removed.
12	Number 3 in the materials that you brought with		Q. Okay. Is it your opinion that after
13	you today?	13	the mesh is separated from the tissue that
14	A. Yes, I do. I'm looking for it. Here	14	there's no longer any protein material on the
15	it is right here, de Tayrac.	15	mesh?
16	Q. When did you obtain your copy of	16	A. No, I believe there still is some
17	Exhibit Number 3, which is an article published	17	protein on the mesh. We can see it, we can see
18	in the by Renaud de Tayrac and Vincent	18	tissue, bits and pieces.
19	Letouzey, it appears in International	19	Q. All right. Are you familiar with the
20	Urogynecology Journal in 2011? When did you	20	term known as biofilm?
21	first receive that?	21	A. Yes.
22	A. I don't recall exactly, because I	22	Q. What do you understand a biofilm to
23	receive so many articles. I remember reading it	23	be?
24	fairly recently, within the last two weeks.	24	A. Well, biofilm would be a covering
25	Q. Did you have a chance to review	25	material that coats things in the body. As far
	Page 55		Page 57
1	Exhibit 3 prior to the time that you conducted	1	as its chemical composition, I've never seen it
2	your work in Exhibits 1 and 2?	2	described in these papers that I've read any
3	A. No.	3	more than to say biofilm. But obviously
4	Q. If you turn to Page 778 of Exhibit 3,	4	protein, probably glycoproteins.
5	read as much as you need to.	5	Q. Would you expect a biofilm to surround
6	A. 778?	6	the mesh that is in the explant samples that you
7	Q. That's right. You're on the right	7	analyzed?
8	page.	8	MR. ANDERSON: Objection.
9	A. This is 780 in mine.	9	Go ahead.
10	MR. ANDERSON: Top right.	10	A. I think that's a very distinct
11		_	
	A. Got it. Top left.	11	
	A. Got it. Top left. MR. ANDERSON: Top left, yes.	11 12	possibility that would be there. Whether it
12	MR. ANDERSON: Top left, yes.	12	possibility that would be there. Whether it would totally surround it or not, I would have
12 13	MR. ANDERSON: Top left, yes. A. All right.	12 13	possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM.
12 13 14	MR. ANDERSON: Top left, yes. A. All right. MR. ANDERSON: After you finish	12 13 14	possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM. BY MR. THOMAS:
12 13 14 15	MR. ANDERSON: Top left, yes. A. All right. MR. ANDERSON: After you finish de Tayrac, can we take a break?	12 13 14 15	possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM. BY MR. THOMAS: Q. All right. Did you make any effort in
12 13 14 15 16	MR. ANDERSON: Top left, yes. A. All right. MR. ANDERSON: After you finish de Tayrac, can we take a break? MR. THOMAS: Sure. Take a break right	12 13 14 15 16	possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM. BY MR. THOMAS: Q. All right. Did you make any effort in your sample preparation as reflected on Page 16
12 13 14 15 16 17	MR. ANDERSON: Top left, yes. A. All right. MR. ANDERSON: After you finish de Tayrac, can we take a break? MR. THOMAS: Sure. Take a break right now if you'd like to.	12 13 14 15 16 17	possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM. BY MR. THOMAS: Q. All right. Did you make any effort in your sample preparation as reflected on Page 16 of Exhibit Number 1 to remove all protein
12 13 14 15 16 17	MR. ANDERSON: Top left, yes. A. All right. MR. ANDERSON: After you finish de Tayrac, can we take a break? MR. THOMAS: Sure. Take a break right now if you'd like to. MR. ANDERSON: Sure.	12 13 14 15 16 17 18	possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM. BY MR. THOMAS: Q. All right. Did you make any effort in your sample preparation as reflected on Page 16 of Exhibit Number 1 to remove all protein materials or biofilms from the mesh before
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12 13 14 15 16 17 18 19 20 21 22 23	MR. ANDERSON: Top left, yes. A. All right. MR. ANDERSON: After you finish de Tayrac, can we take a break? MR. THOMAS: Sure. Take a break right now if you'd like to. MR. ANDERSON: Sure. MR. THOMAS: Let's do that. (Whereupon, a recess was taken from 10:13 a.m. to 10:25 o'clock a.m.) BY MR. THOMAS: Q. Let's go back and make this more	12 13 14 15 16 17 18 19 20 21 22 23	possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM. BY MR. THOMAS: Q. All right. Did you make any effort in your sample preparation as reflected on Page 16 of Exhibit Number 1 to remove all protein materials or biofilms from the mesh before analysis? A. No, we did not. We didn't want to take tremendous efforts in effort is not the right word. But we didn't want to do anything that would try to disturb the mesh.
12 13 14 15 16 17 18 19 20 21 22	MR. ANDERSON: Top left, yes. A. All right. MR. ANDERSON: After you finish de Tayrac, can we take a break? MR. THOMAS: Sure. Take a break right now if you'd like to. MR. ANDERSON: Sure. MR. THOMAS: Let's do that. (Whereupon, a recess was taken from 10:13 a.m. to 10:25 o'clock a.m.) BY MR. THOMAS:	12 13 14 15 16 17 18 19 20 21 22	possibility that would be there. Whether it would totally surround it or not, I would have to look at a specific SEM. BY MR. THOMAS: Q. All right. Did you make any effort in your sample preparation as reflected on Page 16 of Exhibit Number 1 to remove all protein materials or biofilms from the mesh before analysis? A. No, we did not. We didn't want to take tremendous efforts in effort is not the right word. But we didn't want to do anything

15 (Pages 54 to 57)

Page 58 Page 60 1 1 tissue off, and the SEM was actually taken on Q. And de Tayrac finds that the 2 2 degradation is due to the biofilm, correct? the fibers imbedded in the tissue so that we 3 3 A. That's what the paper says. didn't have to pull the fibers out. Because we 4 4 were afraid that with forceps we might cause Q. Do you disagree with that? 5 5 scarring of the surface, and we didn't want to A. I do. 6 6 Q. Why? cause anything like that if we could avoid it. A. It's best showing you in my picture. 7 7 So that was done to -- we didn't even remove the 8 tissue in that case for the SEM work, because we 8 Can I show you a figure? 9 9 didn't want to risk injuring the fibers. Q. Okay. 10 Now, we had to get the fibers clear to 10 A. Go to the FTIR section of my report, 11 11 do DSC, FTIR, GPC, so that's why the tissue was I'll give you a page here in a minute, Page 71, 12 removed for those studies. 12 for example. There's a number of pages. 71 is 13 13 Q. You are aware that using forceps to as good as any, I guess. 14 separate the tissue from the mesh can impact the 14 There's protein here, and as evidenced 15 physical integrity of the mesh? 15 by the 1653, the 1531, amide 1, and amide 2 16 16 MR. ANDERSON: Objection. bands. But there's also polypropylene, 1445, 17 17 1377, and then the four little atactic bands Go ahead. 18 18 that are shown to the right of the 1377 band. A. We were very gentle in how we did 19 this, and it's described in our procedure. We 19 And since the alkyl bands are less intense than 20 tried every way we possibly could to take great 20 the carbonyl bands of the protein, or any other care to not disturb the mesh. So with forceps 21 21 carbonyl types, this would be about a 75 percent 22 22 polypropylene, give or take a little, and maybe we could grab two pieces of tissue and not ever 23 23 touch the mesh to pull it apart. 25 percent protein, or what you would call 24 BY MR. THOMAS: 24 biofilm. 25 Q. Okay. But you made no further effort 25 So this is the stuff that they Page 59 Page 61 to clean the mesh to remove any protein or actually removed with their dimethyl sulfoxide 2 biofilm that remained after removing the mesh 2 their sonication treatment, so it was already 3 with the forceps, correct? 3 gone. 4 A. Correct. 4 But what we did was we actually rolled 5 Q. Now, you've now read de Tayrac, and 5 one of the fibers, and then took the pieces that б de Tayrac analyzes the results that Clavé found б came off, the same pieces they got off in their 7 7 in his study, correct? Figure 1 shown in section B here, Figure 1, we 8 8 A. That's correct. ran the infrared of the pieces that actually 9 Q. And they state on Page 778, "We also 9 came off, and it wasn't biofilm, it was experimentally tested Clavé's conclusion 10 polypropylene. 10 11 regarding a correlation between infection and 11 Q. Dr. Jordi, do you find any polypropylene 'degradation'." 12 methodological flaw in de Tayrac's decision to 12 13 A. Where are you, sir? 13 wash the explants used in his experiment with Q. The very first, Page 778. 14 14 dimethyl sulfoxide and using ultrasonic shock? 15 15 A. If you have -- I certainly do. If you Q. "Using the same method of mesh 16 take a material that's cracked and crazed as we 16 17 infection, we also experimentally tested Clavé's saw in our SEMs, and as he shows here in his 17 18 conclusion regarding a correlation between 18 Figure A on Page 778, that material is going to infection and polypropylene 'degradation'." 19 be very susceptible to flaking off. 19 20 And what de Tayrac did was they washed 20 When I look at 778, Figure A, I see 21 21 their mesh with dimethyl sulfoxide and used what probably is biofilm looking like that cloud 22 ultrasonic shock, and then analyzed the 22 material on top of the polypropylene, and the 23 explanted mesh by electron scanning microscope, 23 polypropylene underlying it, which was then 24 24 blown off. Ultrasonic treatment is kind of -correct? 25 25 A. Correct. is a shock treatment, and it's like putting a

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Page 62 Page 64 1 1 bomb on the polypropylene fiber, so it's going Q. My question is; have you ever done 2 2 to shake off anything that's loose, which it did that? 3 very beautifully, we know that's what it does, 3 A. No, not to this point. 4 4 and it did a beautiful job. Q. And is there any reason other than the 5 5 Unfortunately, the stuff that came off FTIR analysis that you've just described on 6 6 wasn't biofilm, are at least it wasn't totally Page 71 and other places in your report --7 7 A. Correct. biofilm, it wasn't even 50 percent, the majority 8 of it was polypropylene. At least in my case. 8 Q. -- that supports your opinion that 9 9 I can't speak to their -- without actually doing de Tayrac is wrong? 10 the IR of the flaked materials in theirs, I 10 MR. ANDERSON: Objection to form. 11 11 can't tell you a percentage, or even an Go ahead. 12 12 estimate. A. I think the infrared speaks for 13 13 If they had run an IR, which they itself. It's -- in my view as a chemist, a 14 14 didn't do -- I'd like to know why they didn't polymer chemist, it's pretty locked tight. You 15 run an IR to see what it was, they just state 15 can't get polypropylene infrared bands if 16 16 that it's biofilm with no proof. polypropylene isn't there. 17 Q. Have you attempted to clean a mesh 17 BY MR. THOMAS: 18 18 explant and run the same tests that you ran in Q. Is that the -- my question is simple. 19 Exhibit 1 and Exhibit 2 to determine if your 19 Is that the only information that you have, 20 findings are consistent with cleaned explanted 20 based on your analysis and work on this case, 21 21 mesh? that confirms for you that de Tayrac is wrong? 22 22 A. Cleaned how? MR. ANDERSON: Objection. 2.3 23 A. That de Tayrac is wrong. I think I Q. Let me ask it this way. 24 Is there a way in your training, 24 would say yes. I mean we do have other evidence 25 education, and experience to clean the mesh and 25 like DSC perhaps, but we have to -- that wasn't Page 63 Page 65 1 remove biofilms and proteins to allow for the 1 run here either, so I have no data from the 2 analysis of the explanted mesh as cleaned? 2 paper with which to judge the question. 3 A. Yes, there is. I've become aware of 3 BY MR. THOMAS: 4 this since this original work was done. It's 4 Q. You rely on the FTIR analysis in your 5 sodium hypochlorite. 5 report in Exhibit Number 1 and Exhibit Number 2 Q. And tell me how you use sodium 6 б in support of your belief that de Tayrac's 7 7 hypochlorite to clean proteins or mesh before conclusion that what is seen in the SEM is 8 8 you do the analysis? biofilm to be incorrect, is that fair? 9 A. You just soak the sample, the fiber 9 A. That's fair. 10 mesh in this case, in the typically 13 percent 10 Q. Back to oxidation. 11 chlorine solution of sodium hypochlorite. 11 Do you have an opinion about what Q. Have you done that? 12 caused the oxidation that you've identified in 12 13 13 A. We did not do that in this work. your report? Q. Have you done that at any other time? 14 14 A. I believe there was two major reasons. 15 A. No. Not at this point we haven't. 15 One was lack of antioxidant, making Q. Have you ever gone -- strike that. 16 the polypropylene vulnerable to attack by 16 Have you ever tried to replicate --17 hydrogen peroxide and other things, from 17 18 start over one more time. 18 macrophages and so on in the body. Dr. Jordi, have you ever tried to take 19 19 And the other was environmental stress 20 an explanted mesh, remove biofilm or other 20 cracking, which DSC suggests because of the 21 21 protein material, and test it to see the extent decrease in the Delta H at melt, and the 22 to which it had degraded? 22 increase in amorphous content of certain of the 23 A. I really didn't need to do that in 23 polymers, and what seems to happen is some 24 this case because the SEM photographs were so 24 samples seem to have a mix of both, and some 25 25 would be a preponderance of environmental stress

17 (Pages 62 to 65)

Page 66 Page 68 1 1 cracking and other damage, and another would be Doctor, do you have an opinion as to 2 2 caused by classical oxidation mechanism. And what substances in the human body cause the 3 3 the majority of samples in this case seemed to Ethicon polypropylene mesh to lose the 4 4 have both. But it's possible to have just one antioxidants that you've identified in your 5 5 or the other as well. report? 6 6 Q. Do you have an opinion as to whether MR. ANDERSON: Objection. Asked and 7 7 answered. the polypropylene in the Ethicon mesh -- strike 8 that. 8 Go ahead. 9 9 What is it about the human body, the A. It just bleeds, it bleeds out because 10 biochemistry of the human body, that causes the 10 of the nature of the -- we call it blooming in antioxidants to be depleted from the mesh? 11 the industry. Materials leach out of the 11 12 12 MR. ANDERSON: Objection. polymers that they're in, even in air to some 13 13 Go ahead. degree, and then they come on the surface and 14 14 A. I don't know if that's the right get wiped away. So this would be a slow 15 question. If I can explain? 15 process, which is why I believe the papers BY MR. THOMAS: 16 16 typically show no initial oxidation. It has to Q. Please. 17 17 be in the body for a while before you see the 18 18 A. If I were to put polypropylene mesh in major amounts of these effects. 19 a solvent like methylene chloride or ethanol or 19 BY MR. THOMAS: 20 propanol or methanol, or any organic solvent, 20 Q. How long? 21 21 the antioxidants would bleed out at a certain A. Some of the papers say three months. 22 22 rate. And the problem here is the mesh is fine, Q. Do you have an opinion about how long 23 23 so it's a relatively small-ish diameter so a mesh has to be in the body before the 24 there's not a lot of distance from the internal 24 antioxidants are depleted to the point where the 25 part of the fiber to the surface. So if I put 25 mesh can degrade? Page 67 Page 69 1 it in solvent, it's going to bleed out. If I 1 A. No, we would have to do a study, a 2 put it in the body which is full of lipids, 2 time study to answer that question, where we 3 cholesterol, phospholipids, cholesterol, 3 actually measured -- right now we've just 4 cholesterol esters, fatty acids, it's going to 4 measured levels of antioxidant in the samples 5 5 be bleeding out there. But it would bleed out received, the explants and the controls. We 6 б in either place. It's not really a phenomenon I would have to do a time study to answer that 7 7 see that's unique to the human body, it would question where we'd do three months, six months, 8 8 happen either place, and so it just bleeds out nine months, a year, five years, however long we 9 because of the high -- relative high surface 9 wanted to do the study, and measure the amount 10 area and small diameter. 10 of the two antioxidants present as a function of 11 Q. Do you have an opinion of what 11 time. specifically it is about the human body that 12 12 Q. Is the sole basis for your opinion 13 causes the Ethicon polypropylene mesh to leak, 13 that the Ethicon polypropylene mesh at issue in 14 leach its antioxidants? 14 this litigation leaches its antioxidants the testing that's reflected in Exhibits 1 and 2? 15 A. I don't think -- as I say, I don't 15 think that is the right question. It's going to 16 A. Yes. 16 17 leach wherever it is in any solvent. 17 Q. A moment ago I asked you about the 18 It wouldn't leach in water, obviously, 18 causes, I think, of degradation, and you said 19 oxidation in combination with, in some 19 because it's not soluble, or not wetted by 20 water. But anything that will wet it, whether 20 instances, environmental stress cracking? 21 it's a fatty acid or whether it's a solvent, 21 A. Correct. 22 fatty acid in the body or a solvent, is going to 22 Q. We also talked earlier about 23 cause it to remove, I guess, the fatty -- the 23 mechanical degradation. Is there any evidence 24 antioxidants that are bleeding to the surface. 24 of mechanical degradation in your work in either 25 Exhibits 1 and 2? 25 Q. Let me ask it this way.

18 (Pages 66 to 69)

1 2	Page 70		Page 72
	A. No. That's a minor player here. If	1	BY MR. THOMAS:
ı /.	any effect, it would have to do during the	2	Q. What are you reading?
3	manufacturing phase. When the polymer is put	3	A. I am looking at I'm looking for a
4	through the dye, it will be extruded under	4	paper that shows the I don't know whether
5	stress, that's mechanical force, and that will	5	it's it's either Liebert or Turi, Oswald and
6	tend to sheer polymer chains and tend to	6	Turi.
7	degrade. But that's the only application.	7	Q. I'll help you here a little bit.
8	Certainly in the human body I don't see any	8	(Whereupon, Jordi Exhibit Number 4,
9	major application of stress, mechanical stress.	9	Liebert, et al study titled
10	Q. Okay. So can we confine our	10	Subcutaneous Implants of Polypropylene
11	discussion today of degradation in terms of	11	Filaments, was marked for
12	oxidation and environmental stress cracking?	12	identification.)
13	A. I think so.	13	BY MR. THOMAS:
14	Q. Dr. Jordi, if the mesh antioxidant	14	Q. Let me show you what's been marked as
15	additives remained in the mesh, would the mesh	15	Exhibit Number 4. Exhibit Number 4, is that the
16	be able to perform its function in the body	16	Liebert study to which you were just referring?
17	without oxidizing?	17	A. 1976, yes, I believe, yes.
18	A. I think that's suggested in the	18	Q. And in Liebert they studied meshes
19	literature, yes.	19	that had been treated with oxidants excuse
20	Q. Okay. Do you agree with what the	20	me, treated with antioxidants and meshes that
21	literature says, that is; if the mesh maintains	21	had not, correct?
22	its antioxidants that it's able to perform its	22	A. Correct.
23	function in the body as intended?	23	Q. And found that those that had been
24	A. It certainly would I don't know	24	that had antioxidants added to them did not
25	that I can answer the question completely, but	25	degrade like those that did not have
	Page 71		Page 73
1	it certainly would increase the longevity of the	1	antioxidants, correct?
2	product for sure.	2	A. That's right, showing that, yes.
3	Q. Okay. Do you have an opinion that the	3	
			O Is that the basis strike that
	mach with the antiovidante that etay there is		Q. Is that the basis strike that.
4	mesh with the antioxidants that stay there is	4	Is that the literature upon which you
4 5	unsafe for its intended purpose without more?	4 5	Is that the literature upon which you rely for your statement just a minute ago that
4 5 6	unsafe for its intended purpose without more? MR. ANDERSON: Objection as to form.	4 5 6	Is that the literature upon which you rely for your statement just a minute ago that those meshes with antioxidants in them resist
4 5 6 7	unsafe for its intended purpose without more? MR. ANDERSON: Objection as to form. Go ahead.	4 5 6 7	Is that the literature upon which you rely for your statement just a minute ago that those meshes with antioxidants in them resist degradation?
4 5 6 7 8	unsafe for its intended purpose without more? MR. ANDERSON: Objection as to form. Go ahead. A. Without more?	4 5 6 7 8	Is that the literature upon which you rely for your statement just a minute ago that those meshes with antioxidants in them resist degradation? A. Well, it's that, and it's my lifetime
4 5 6 7 8 9	unsafe for its intended purpose without more? MR. ANDERSON: Objection as to form. Go ahead. A. Without more? BY MR. THOMAS:	4 5 6 7 8 9	Is that the literature upon which you rely for your statement just a minute ago that those meshes with antioxidants in them resist degradation? A. Well, it's that, and it's my lifetime of experience analyzing polypropylenes, and when
4 5 6 7 8 9	unsafe for its intended purpose without more? MR. ANDERSON: Objection as to form. Go ahead. A. Without more? BY MR. THOMAS: Q. I'm just trying to narrow the scope	4 5 6 7 8 9	Is that the literature upon which you rely for your statement just a minute ago that those meshes with antioxidants in them resist degradation? A. Well, it's that, and it's my lifetime of experience analyzing polypropylenes, and when they degrade and when they don't.
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Page 76 Page 74 1 their free form. But the Fenton reaction is 1 in Japan, 100,000 seat stadium. The seats in 2 2 one year from installation turned to dust and 3 3 blew away. So they had sent me some retains, Q. You call it the Fenton reaction? 4 4 and I had to analyze it, and the polypropylene A. Fenton reaction, yes. 5 was not stabilized. And so that's part of my 5 Q. Okay. If hydrogen peroxide was the 6 6 lifetime of experience. cause of the degradation of the polypropylene 7 7 mesh, would there be a change in the molecular Another case, the client was suing a 8 motorcycle manufacturer because -- for a 8 structure of polypropylene? 9 9 defective gas tank. But he'd hit a brick wall A. Repeat the question, please? I'm 10 at a very high rate of speed, I don't remember 10 sorry. the exact, 75, 80 miles an hour, and the gas 11 11 Q. If the hydrogen peroxide that you 12 tank ruptured and exploded. And so they were 12 described was the cause of the degradation in 13 13 the polypropylene mesh, would there be a change blaming the manufacturer. So I had to analyze a 14 bit of that. In that case the stabilizers were 14 in the chemical structure of the polypropylene 15 present. And the point was no gas tank is going 15 mesh? 16 16 to survive hitting a brick wall at 75, 80 miles A. That's right, there would be. 17 17 an hour, so -- even though the stabilizer was Q. If there was a free radical that 18 there. So it wasn't degraded, molecular 18 degraded the polypropylene mesh, would there be 19 weight-wise, it wasn't degraded, the 19 a change in the chemical construction of the 20 antioxidants were there. 20 polypropylene mesh? 21 21 And in the other case, it turned to A. Yes. You would be inserting oxygen 22 22 dust and blew away, and the antioxidants were into the chain in the form of either ketone, 23 2.3 aldehyde, hydroxide. not present. 24 So when I see a lack of antioxidant in 24 Q. And the free ferrous ion which you 25 essentially basically all these samples, by both 25 referred to as the Fenton? Page 75 Page 77 1 PYMS and LCMS, it tells me the polymer is 1 A. It's not just a free -- if you would 2 exceedingly susceptible to oxidation by hydrogen 2 like I'll give you the reaction. Do you want 3 peroxide, which it would be partially protected 3 that? 4 from if antioxidants were still there, but 4 Q. Yes. 5 5 they're not there. A. Fe2+ plus hydrogen peroxide goes to, 6 б Q. Okay. Is it your opinion that an arrow, Fe3+ +HO- -- that's hydroxide, that's 7 7 hydrogen peroxide is the material that attacked harmless, but here's the problem -- +HO., which 8 8 the mesh that caused it to degrade as is is the radical, hydroxy radical, that is many 9 reflected in Exhibits 1 and 2? 9 more times damaging to polypropylene than the 10 A. Well, in the body there are things 10 initial hydrogen peroxide. Q. Okay. 11 like ferrous ion, for example, and if -- I can't 11 12 A. Now, I can't sort out which one is --12 answer the question with a simple answer 13 because, again, there's multiple causes. 13 Q. That's fine. You're consulting a 14 If there's any free ferrous ion around 14 paper there. What's the paper you're 15 you'll get what's called a Fenton reaction, 15 consulting? which converts hydrogen peroxide to hydroxyl 16 A. "Mechanisms of polymer degradation in 16 17 implantable devices" by Williams. radicals, which are more damaging than the 17 18 hydrogen peroxide to begin with in causing 18 Q. That's David Williams? degradation of the polypropylene. It's a free 19 A. David Williams. 19 20 radical initiator step. 20 Q. That's the one cited in your --A. Yes, sir. 21 So if there is, you know, bleeding 21 22 perhaps, that can be a source of iron, and if 22 Q. Okay. The last reaction you described 23 there's some ferrous ion around -- of course it 23 is called the Fenton reaction, is that right? 24 has to be free ferrous ion, the body needs 24 A. Right. 25 25 protein to bind iron, because it's dangerous in Q. Does the Fenton reaction causing

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1 2	Page 78		Page 80
	degradation of polypropylene alter the chemical	1	A. Those are described in actual tests in
	structure of the polypropylene?	2	the Dr. Müller book, timed experiments.
3	A. Does the hydroxide or the Fenton	3	Q. Do you know?
4	reaction cause, is that what you're asking.	4	A. Well, it depends on the temperature.
5	Q. Yes.	5	And it varies with the environment, the oxygen
6	A. Sure it does, because that's the	6	environment and the temperature actually used.
7	production of the hydroxy radicals which causes	7	Some are run at 200 degrees, some are run at
8	the actual change.	8	100 degrees.
9	Q. Any other potential sources of	9	Q. Do you know the temperature at which
10	oxidation to the polypropylene mesh given the	10	the polypropylene that's used in the Ethicon
11	leaching of antioxidants that you've described?	11	mesh will degrade?
12	MR. ANDERSON: Objection as to form.	12	A. I know in general terms that the
13	Go ahead.	13	higher the temperature, the faster it will
14	A. You could also have what's called a	14	degrade. That's what I know. Which is
15	more general version of the Fenton reaction,	15	uniformly true.
16	would be the Haber-Weiss, H-A-B-E-R - W-E-I-S-S,	16	Q. Do you have an opinion as you sit here
17	reaction.	17	today of the temperature at which the Ethicon
18	BY MR. THOMAS:	18	mesh used in the TVT device will degrade?
19	Q. Are you consulting the Williams	19	A. Without testing, no. And it would
20	article again?	20	depend on whether the antioxidants are there or
21	A. Yes. That would be include cuprous	21	not, that will affect the temperature.
22	ion as well as ferrous ion, could include	22	Q. Is it possible to measure the amount
23	titanium is another one, titanium 3 or vanadium	23	of hydrogen peroxide that is in a person around
24	4 is another possibility. Those are not	24	the mesh implant?
25	commonly found, we're not going to worry about	25	A. We have techniques that will allow us
	Page 79		Page 81
1	those in the body.	1	to measure hydrogen peroxide. We have hydrogen
2	Q. Titanium and vanadium aren't going to	2	peroxide test strips, for example, but you can't
3	be found in the body, are they?	3	stick those into an implant very well. So I
4	A. No. It's cuprous and ferrous.	4	don't know, I've never seen it talked about or
5	Q. Are all of the potential methods of	5	done anywhere.
	degradation for the polypropylene mesh that	6	A no seem alala ta tant fantlan massanan
6	you've identified in the human body in the		Q. Are you able to test for the presence
7	you've identified in the human body in the	7	of hydrogen peroxide on the explants that you
7 8	Williams article that you're consulting?	8	of hydrogen peroxide on the explants that you analyzed?
7 8 9	Williams article that you're consulting? A. Well, they're certainly in there.	8 9	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips
7 8 9 10	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well.	8 9 10	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but
7 8 9 10 11	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods	8 9 10 11	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in
7 8 9 10 11 12	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors?	8 9 10 11 12	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed
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7 8 9 10 11 12 13	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in	8 9 10 11 12 13 14	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today,
7 8 9 10 11 12 13 14	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article?	8 9 10 11 12 13 14 15	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples
7 8 9 10 11 12 13 14 15	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article? A. Well, you could get R., which is the	8 9 10 11 12 13 14 15	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of
7 8 9 10 11 12 13 14 15 16 17	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article? A. Well, you could get R., which is the radical form of polypropylene, just from heat to	8 9 10 11 12 13 14 15 16	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of any of the materials that you've just identified
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7 8 9 10 11 12 13 14 15 16 17 18	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article? A. Well, you could get R., which is the radical form of polypropylene, just from heat to some degree, so that's why heat would cause radical formation also.	8 9 10 11 12 13 14 15 16 17 18	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of any of the materials that you've just identified that could contribute to the degradation of the mesh?
7 8 9 10 11 12 13 14 15 16 17 18 19 20	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article? A. Well, you could get R., which is the radical form of polypropylene, just from heat to some degree, so that's why heat would cause radical formation also. Q. How much heat would require	8 9 10 11 12 13 14 15 16 17 18 19 20	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of any of the materials that you've just identified that could contribute to the degradation of the mesh? A. Well, no, I don't think so, not as
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article? A. Well, you could get R., which is the radical form of polypropylene, just from heat to some degree, so that's why heat would cause radical formation also. Q. How much heat would require A. I don't think the human body, we'd	8 9 10 11 12 13 14 15 16 17 18 19 20 21	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of any of the materials that you've just identified that could contribute to the degradation of the mesh? A. Well, no, I don't think so, not as received.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article? A. Well, you could get R., which is the radical form of polypropylene, just from heat to some degree, so that's why heat would cause radical formation also. Q. How much heat would require A. I don't think the human body, we'd have to worry too much in the human body. We're	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of any of the materials that you've just identified that could contribute to the degradation of the mesh? A. Well, no, I don't think so, not as received. Q. You don't know, or you don't think you
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article? A. Well, you could get R., which is the radical form of polypropylene, just from heat to some degree, so that's why heat would cause radical formation also. Q. How much heat would require A. I don't think the human body, we'd have to worry too much in the human body. We're talking processing now.	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of any of the materials that you've just identified that could contribute to the degradation of the mesh? A. Well, no, I don't think so, not as received. Q. You don't know, or you don't think you could?
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Williams article that you're consulting? A. Well, they're certainly in there. Other authors describe that as well. Q. Okay. Are there any other methods described by other authors? A. Other methods? Q. Yes. Have we covered all the bases in the Williams article? A. Well, you could get R., which is the radical form of polypropylene, just from heat to some degree, so that's why heat would cause radical formation also. Q. How much heat would require A. I don't think the human body, we'd have to worry too much in the human body. We're	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of hydrogen peroxide on the explants that you analyzed? A. You could try to use those test strips and see if the strips turn blue if but likely, it's been stored in the formaldehyde in getting to us, so it's all going to be washed off anyway. Q. Do you know, as you sit here today, whether you can test the explanted mesh samples that you received to determine the presence of any of the materials that you've just identified that could contribute to the degradation of the mesh? A. Well, no, I don't think so, not as received. Q. You don't know, or you don't think you

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Page 82 Page 84 cannot? 1 1 of metals that would be the catalyst for the 2 2 A. Cannot. Haber-Weiss reaction or the Fenton reaction. 3 Q. Thank you. 3 Q. If you had that information, how would 4 4 A. Because it's not there, it's been you use that to determine the extent to which 5 treated with formaldehyde when we get it, so 5 those chemicals caused or contributed to the 6 6 it's not the way it was in the body -degradation of the mesh? 7 7 Q. Okay. A. Well, the greater the concentration of 8 A. -- at the time of excision. 8 the iron and copper, copper 2 and iron -- copper 9 9 Q. So is it fair to understand that it's 1 and iron 2, the greater the damage would be. 10 your opinion that you're not able to test these 10 Q. Okay. 11 A. It should correlate. But it's mesh explants for materials that may have been 11 12 in the body that you believe caused or 12 complicated, because if those metals were tied 13 13 contributed to the degradation of the mesh? up by the typical proteins in the body that are MR. ANDERSON: Objection to form. 14 14 supposed to tie up copper and iron so they are 15 Materials in the body, or chemicals in 15 not -- they don't kill us, you have to figure 16 16 out a way to -- and as I sit here, this is just the body? 17 17 research, I'm unable to answer the question MR. THOMAS: Thank you, Ben. MR. ANDERSON: Just to be clear. 18 completely, I would have to be sure that the 18 19 BY MR. THOMAS: 19 iron we determined was free ferrous ion in the 20 Q. Doctor, is it fair to understand it's 20 body and free cuprous, or it wouldn't be 21 21 your opinion that because of the placement of damaging even if present. 22 the explants in formaldehyde, that one is unable 22 Sorry, that's my answer. 2.3 23 to test for chemicals in the body that may have Q. Okay. Let me see if I can finish 24 caused or contributed to the degradation of the 24 this. 25 mesh? 25 Is it fair to understand, Doctor, as Page 83 Page 85 1 A. That question would require a lot of 1 you sit here today you don't know of a test that 2 research. But it's possible, for example, that 2 would enable you to determine which chemicals in 3 we could -- certainly we could look for iron in 3 the body caused or contributed to any 4 the tissue, or we could look for copper in the 4 degradation of the mesh explant samples? 5 tissue, which would be consistent with the 5 A. No. We just know that macrophages б Haber-Weiss reaction, which would have produced б have been shown to -- in superoxide and hydrogen 7 the hydrogen peroxide in the first place. So we 7 peroxide. 8 8 could see telltale signs. In that sense, we Q. Okay. You said "no" to my question. 9 might be able to see something. 9 A. I'm sorry. Correct. 10 10 Q. Doctor, as you sit here today, is Q. Is it true, is it fair to say that, as 11 there a test that you know of that could be 11 you sit here today, that you don't know of any performed on these explanted meshes to determine 12 tests that would allow you to determine which 12 13 which chemical substance in the body caused or 13 chemicals in the body may have caused or 14 14 contributed to any degradation of this mesh? contributed to any degradation of the mesh 15 A. If it's hydrogen peroxide produced in 15 explant samples? the macrophages, we can't test for it because 16 A. Again, from my reading the literature 16 17 and seeing the production of hydrogen peroxide 17 it's not there. 18 Q. Okay. Anything else? 18 and superoxide, that has to be one of the A. If it's caused by the Fenton reaction 19 mechanisms, and the other ones could be. I 19 20 or the Haber-Weiss, yes, we could take that 20 don't know how to answer the question. tissue, and we could dissolve it, and then run 21 21 Q. But the question is; it's fair to 22 ion chromatography and determine parts per 22 understand, as you sit here today, that you do 23 billion levels of iron and the copper. 23 not know of any test that you could perform to 24 Q. What would that tell you? 24 determine which chemicals in the body may have 25 25 A. It would tell us the potential levels caused or contributed to any degradation of the

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Page 86 Page 88 polypropylene mesh in these explants? You don't 1 1 amount of crystallinity goes down. Delta H of 2 2 know of one? melt goes down, the percent crystallinity goes 3 3 down, the percent amorphous goes up, which then A. Seeing the oxidation, I couldn't tell 4 4 you whether it was caused by the Fenton that material, the amorphous material, is what 5 reaction, the Haber-Weiss reaction, or hydrogen 5 is susceptible to environmental stress cracking. 6 6 peroxide, that's true, if that's what you want. BY MR. THOMAS: 7 7 Q. Thank you. Q. Doctor, do you have an opinion in this 8 Or any other substance, there's not a 8 case as to whether the mesh explants that you 9 9 test that you can do to tell us what caused it? analyzed show environmental stress cracking? 10 A. No. All I can say is I'm looking at 10 A. I think as one of the components I 11 11 the fact of the degradation. It had to happen, have an opinion, because we saw a drop in the 12 so I'd be looking for -- as to what specifically 12 Delta H at melt, of the explants. 13 13 caused it, I have to agree. Q. Is it your opinion that the drop in 14 the Delta H in the DSC testing is proof of 14 Q. Thank you. 15 A. I can't answer. 15 environmental stress cracking? MR. THOMAS: We can take a quick break 16 16 A. It's just like the lack of 17 17 antioxidants. It's consistent with, it's not by if you don't mind. 18 itself proof of. But it's proof of the 18 (Whereupon, a recess was taken from 19 11:06 a.m. to 11:15 a.m.) 19 susceptibility of the polymer to environmental 20 BY MR. THOMAS: 20 stress cracking. 21 21 Q. Doctor, what is environmental stress Then I have to go back still, 22 22 ultimately back to the SEMs, because the fact is cracking? 23 23 A. Environmental stress cracking is the not in question. It's occurring, we can see it. 24 degradation of a polymer from imbibing, or the 24 The question is why, and that way we have to --25 absorption of materials, in this case like 25 now we have to look at a series of data to make Page 87 Page 89 1 cholesterol, cholesterol esters, fatty acids, 1 our best judgment. I think in many cases the 2 into the interstitial space between the polymer 2 damage is caused by both. 3 chains which causes it to swell, creating 3 Q. So just so I'm clear, your opinion 4 stress, which eventually ruptures some of the 4 that the mesh that you've analyzed in the 5 5 polymer chains, causing degradation. explants has undergone environmental stress 6 б Q. Is it your opinion in this case that cracking is due to your visual observation on 7 7 the mesh explants that you analyzed exhibit the SEM images and the DSC data, correct? 8 8 environmental stress cracking? A. Right. 9 A. Sorry. Repeat the question, please? 9 Q. Is there any other information that 10 Q. Is it your opinion in this case that 10 you determined from your report, or your work in 11 the mesh explants that you analyzed show 11 this case, that you rely upon for your opinion 12 that the explanted mesh underwent environmental 12 environmental stress cracking? 13 MR. ANDERSON: Objection. Asked and 13 stress cracking? 14 answered. 14 A. Any other data from my report, that 15 15 was the question? Go ahead. A. When I look at SEM photographs and see 16 Q. Yes. 16 17 A. No. the cracking, I can't tell just from looking at 17 18 the cracking whether it was oxidative damage or 18 Q. All right. Do you agree that pelvic environmental stress cracking that caused that 19 organ prolapse is well-known for its high 19 20 damage, or a combination of both. 20 resistance to environmental stress cracking? 21 21 DSC is one of the best techniques to A. Yes. But the fact of the matter is 22 suggest that, because we can measure the melt 22 the Delta H is going down, so something is 23 point, and we can measure the Delta H at melt 23 causing that amorphous region to increase. 24 which correlates to the amount of crystallinity. 24 Q. And the Delta H you're talking about 25 25 So as the Delta H of melting goes down, the is the melting point as measured by the DSC

23 (Pages 86 to 89)

	Page 90		Page 92
1	measurements, correct?	1	fatty acids and the like, then the process would
2	A. The melting point goes down, and the	2	be more rapid than they would if there weren't
3	Delta H at melt goes down. And again, there's	3	as much cholesterol, cholesterol esters in a
4	variability from sample to sample. So some	4	given patient. That depends on the patient's
5	samples have more component of potential, I'll	5	disease state, for example, their weight.
6	describe it as potential environmental stress	6	BY MR. THOMAS:
7	cracking, and other samples from less potential.	7	Q. Do you have an opinion in this case
8		8	
9	The same way I would describe the lack of	9	about the expected rate of crack propagation in
10	antioxidant to be potential oxidation.		the mesh implanted in Carolyn Lewis?
	In all cases we are seeing the	10	A. No.
11	degradation through SEM of the polypropylene.	11	Q. Do you have an opinion about the
12	That's just a fact. And we know it's	12	expected mesh excuse me, crack propagation of
13	polypropylene because the infrared spectrum is	13	the mesh implanted in Linda Batiste?
14	that of polypropylene, the flakes.	14	A. Well, the fact of the matter is I can
15	Q. What's crazing?	15	see the cracks, I'm looking at them with SEM.
16	A. Small cracks.	16	That's all I can say.
17	Q. What does crazing have to do with	17	Q. Very specific question.
18	environmental stress cracking?	18	Do you have an opinion about the
19	A. Well, it's the start of the process.	19	expected time for the crack propagation in Linda
20	When you have a little bit of cholesterol ester	20	Batiste?
21	you have just little cracks, little start, it's	21	A. No, I don't.
22	moving in, the process is beginning.	22	Q. Are you able to analyze the mesh
23	Q. Are you familiar with a concept known	23	explants and determine how long the mesh has
24	as crack initiation?	24	been cracked?
25	A. That's what crazing does, is initiates	25	A. No. Just the fact that it is.
	Page 91		Page 93
1	the forming of the larger cracks.	1	Q. Are you able to analyze the mesh
2	Q. So when you have smaller cracks and	2	explants that you've reviewed in this case and
3	things get in there, then the cracks get bigger?	3	determine or measure the extent of the cracking?
4	A. Basically.	4	A. Well, visually it's quite obvious
5	Q. What's crack propagation?	5	that
6	A. Once a material starts to crack, it's	6	Q. I'm talking about quantitatively.
7	like a rip in a garment, it's going to just	7	A. There is no way to do that short of
8	once the rip starts, it's easier to continue it.	8	looking at the pictures, that I'm aware of. I
9	Q. Are you familiar with a concept known	9	don't know anybody using a scale.
10	as fast crack propagation?	10	Q. Do you have an opinion in this case,
11	A. No, I'm not.	11	first of all the Carolyn Lewis case, about the
12	Q. Do you know the extent to which	12	extent to which any degradation in her strike
13		13	that.
	environmental stress cracking in polypropylene		
14 15	could be expected to be slow or fast, or there	14 15	Do you have an opinion in the Carolyn
	in small forms forever? Do you have any idea of		Lewis case about the extent to which any
16	the relative strike that. That's a terrible	16	environmental stress cracking impacts the
17	question.	17	functionality of the polypropylene mesh for its
18	Doctor, do you have any ideas about	18	intended purpose?
19	the expected progress of crack propagation in	19	A. Let me look at the I have to look
20	polymers?	20	at the DSC data.
21	MR. ANDERSON: Objection to form.	21	Q. This is very specific. This is
22	Go ahead.	22	Carolyn Lewis.
23	A. It would depend on the environment	23	A. Correct.

24 (Pages 90 to 93)

Page 96 Page 94 1 1 again? question. 2 2 BY MR. THOMAS: Q. Based upon your review of the mesh in 3 3 this case and your analysis in this case, tell Q. Do you have an opinion in the Carolyn 4 4 Lewis case about the extent to which any me how the oxidation of the mesh in Carolyn 5 5 environmental stress cracking impacts the Lewis impacts the functionality of the 6 6 functionality of the polypropylene mesh for its polypropylene mesh for its intended purpose? 7 7 intended purpose? How does it do it? 8 A. I do not. 8 A. When you get ketones in the polymer, 9 9 Q. Do you have an opinion in the Carolyn aldehydes in the polymer as reflected in these 10 Lewis case about the extent to which any 10 carbonyls, you -- that leads to ultimately to 11 oxidation impacts the functionality of the chain -- what we call chain beta scission, chain 11 12 12 polypropylene mesh for its intended purpose? scission, which is degradation. And besides, it 13 13 MR. ANDERSON: Objection as to form. causes embrittlement in its own right. Very low 14 A. Of oxidation effects the --14 levels of oxygen incorporated into polypropylene 15 BY MR. THOMAS: 15 causes a material to become rigid which is 16 16 Q. Correct. classic of this. 17 A. Now I have to go through and look and 17 Q. What is it about your work in this 18 18 see if -case that causes you to have the opinion that 19 (Witness reviewing document.) 19 the oxidation of the mesh in Carolyn Lewis 20 A. Well, the infrared spectrum on Page 71 20 impacts the functionality of that mesh for its 21 21 is a Carolyn Lewis sample. It has a carbonyl intended purpose? 22 22 band, so the little band that's in front of the A. Oxidation is bad. We see it. 2.3 23 amide 1 is a sign of oxidation. Q. Okay. Are you able to measure the 24 BY MR. THOMAS: 24 amount of oxidation that occurred in Carolyn 25 Q. That's not my question, Doctor. Let 25 Lewis quantitatively? Page 95 Page 97 1 me ask it again. Very specific question. 1 A. No. 2 Do you have an opinion in the Carolyn 2 Q. Can you tell me anything more than 3 Lewis case about the extent to which any 3 oxidation is bad in support of your opinion that 4 oxidation impacts the functionality of the 4 the work in this case shows that the mesh 5 polypropylene mesh for its intended purpose? Do 5 implanted in Ms. Lewis was not able to perform its intended function? б you have a specific opinion in that regard? б 7 7 A. My opinion would be it appears A. The antioxidants were missing. The 8 8 oxidized, so yeah, it would be degraded. material is not protected. I think we see -- we 9 Q. Does it have any have oxidation -- do 9 go over and look at EDX results, if I can 10 you have an opinion about whether the Carolyn 10 find --11 Lewis mesh explant has oxidation that impacts 11 (Witness reviewing document.) the functionality of the polypropylene mesh for 12 BY MR. THOMAS: 12 13 its intended purpose? 13 Q. You can look all you want to. Do you 14 14 A. Any oxidation is bad. I see carbonyl want to continue your answer? I don't think you 15 is oxidation, so yes, my answer is yes, I have 15 answered my question, but you can do whatever an opinion. 16 you think you need to do. 16 17 Q. What is the opinion? MR. ANDERSON: He's trying to ask you 17 18 A. It's damaged. 18 what about the oxidation in Carolyn Lewis, in 19 19 Q. How does the damage that you observed your opinion, affects the function of the device 20 affect the ability of the polypropylene mesh to 20 for its intended purpose. function in its intended purpose? 21 21 A. All oxidation affects the function. 22 A. Well, something had to cause it to 22 MR. ANDERSON: How is what he's asking 23 have it removed. I'm looking at the pictures, 23 you. 24 it's flaking, I'm looking at the oxidation, it's 24 A. It makes it more rigid. It makes it oxidized. I don't know how else to answer the 25 more brittle eventually. It causes it to flake. 25

25 (Pages 94 to 97)

	Page 98		Page 100
1	BY MR. THOMAS:	1	to the extrusion lines, or the grain of the
2	Q. How much oxidation is required for the	2	mesh?
3	mesh to be more rigid?	3	A. Correct.
4	A. I can't answer that question sitting	4	Q. Have you analyzed the extent to which
5	here, but it's not very much from reading the	5	perpendicular cracking is consistent with the
6	literature. 1 percent increased oxygen would	6	chemical structure of the mesh?
7	probably do it.	7	A. Repeat the question, please?
8	Q. How much oxidation is required to make	8	Q. Have you analyzed the extent to which
9	the polypropylene more brittle?	9	perpendicular cracking is consistent with the
10	A. It's a process. It's not a single	10	chemical structure of the mesh?
11	point. So I felt this material in my fingers, I	11	MR. ANDERSON: Objection as to form.
12	could feel the rigidity in it compared to the	12	Go ahead.
13	straight.	13	A. When you put a material through the
14	Q. Very simple question. How much	14	dye, you'll be aligning the polymer chains along
15	oxidation is required, Doctor?	15	the line of the fiber so that only you
16	A. I don't know.	16	basically only have London-London forces of the
17	Q. How many oxidation is required to	17	CH2 groups and CH3 groups in the polymer
18	cause the polypropylene to flake?	18	backbone holding the polymer together, so it
19	A. Anywhere from none to a lot, because	19	will be more easily cracked if you bend it
20	it depends if it was environmental stress	20	it's going to tend to crack vertically to the
21	cracking you wouldn't necessarily to have	21	direction of the fiber.
22	oxidation for environmental stress cracking, or	22	BY MR. THOMAS:
23	it could be totally related to oxidation, or it	23	Q. Okay. Is that something you studied
24	could be a mix.	24	before I asked you the question, or you just
25	Q. Dr. Jordi, you report in Exhibit 1 and	25	answered that question based upon your
	Page 99		Page 101
1	2 the observation of cracking perpendicular to	1	knowledge?
2	the extrusion lines in the mesh?	2	A. Based on my knowledge.
3	A. Yes.	3	Q. Okay. Did you study, as a part of
4	Q. And what are extrusion lines?	4	your analysis of this case, the extent to which
5	A. Well, you just can see them in the	5	cracking would be expected along the grain or
6	I think they're little probably caused by	6	extrusion lines of the mesh as compared to the
7	miniature, if you want to call it, defects in	7	perpendicular angle that's called out in your
8	the dye.	8	report?
9	Page 25 is a typical example. You can	9	MR. ANDERSON: Objection as to form.
10	see the lines moving along the line of	10	A. Again, I have to have it repeated.
11	extrusion.	11	Sorry.
12	Q. Extrusion is a process by which the	12	BY MR. THOMAS:
13	fibers are formed?	13	Q. Did you study, as a part of your
14	A. I believe so, yes.	14	analysis of this case, the extent to which
15	Q. Are you familiar with the extrusion	15	cracking would be expected along the grain or
16	process?	16	extrusion lines of the mesh as compared to the
17	A. Not a lot.	17	perpendicular angle that's called out in your
18	Q. Okay.	18	report?
19	A. I'm more an analyst.	19	A. Well, what's called out in my report
20	Q. Are you comfortable with calling the	20	was what we observed.
	and mark in a line of the angle of the file of	21	Did I study differences? It's not a
21	extrusion lines the grain of the fiber?		
21 22	A. Sure.	22	perfect thing. You can see cracks in other
21 22 23	A. Sure.Q. Okay. And when we talk about the	22 23	perfect thing. You can see cracks in other directions, too, sometimes, it's just a majority
21 22	A. Sure.	22	perfect thing. You can see cracks in other

26 (Pages 98 to 101)

Page 102 Page 104 1 1 A. And furthermore, you can see these -come apart in the amorphous region. They don't 2 2 the grain, as you call it, is running right have as much force holding them together. You 3 3 through these cracks, so that's further have to literally rupture chemical bonds. 4 4 information to suggest that these -- this I don't see what you're saying, I'm 5 5 cracked region is not biofilm, it's sorry. 6 6 polypropylene, because it's got the same grain Q. So is it your testimony that to have 7 7 in it the original polypropylene did in the the oxidation or environmental stress cracking 8 cracked pieces. If it was biofilm, those marks 8 necessary to cause the cracking on Page 40 in 9 9 should go away. They don't, they're there. Figure 44 of your report, Exhibit 1, requires a 10 Q. Have you analyzed the issue of 10 rupture of the chemical bond? 11 11 environmental stress cracking to determine A. I would think that would be true on 12 whether environmental stress cracks would run 12 the surface, yes. 13 13 with the extrusion lines or the grain as opposed Q. Okay. 14 14 A. Has to be. to the perpendicular manner in which you call 15 out in your report? 15 Q. And every place that you see this 16 16 A. Have I analyzed that? No. cracking in the scanning electron microscopy, 17 Q. The crazing that you've talked about 17 the images that you've talked about, in order to 18 18 are the areas in the mesh that are furthest away get the cracking that you describe shown in the 19 from the crystals in the mesh, is that fair, in 19 SEM images requires a breaking of the chemical 20 the amorphous regions? 20 bond; fair? 21 21 A. In the amorphous regions, yes. A. I think so. 22 22 Q. And the crazing that you've talked Q. Let's go to your report, Exhibit 23 about is the small cracks that form in this 23 Number 1. Let's go to the PYMS data. 24 amorphous region, correct? 24 MR. ANDERSON: Page 80 you're showing? 25 A. Yes. 25 MR. THOMAS: Page 80. Page 103 Page 105 1 Q. Knowing what you do about 1 A. Okay. 2 polypropylene, and the chemical structure of it, 2 BY MR. THOMAS: 3 and the crazing that you've just described, 3 Q. Tell me what the PYMS technique is. 4 wouldn't it be more likely that any 4 A. Stands for pyrolysis mass 5 environmental stress cracking would occur with 5 spectroscopy. The sample is heated, and until 6 б the grain or along the extrusion lines of that it fractures the bonds in the polymer releasing 7 7 mesh as opposed to perpendicular to the mesh? everything, small molecules and so on, and then 8 8 A. The -- if you -- well, first of all, those fragments are put through a GC column, 9 the fact of the matter is it's vertical to it. 9 then they're monitored by a mass spectrometer. 10 I mean that's just a fact for the vast majority 10 We tend to do a two step method as 11 of them. 11 well where we heat the sample to 300C, which 12 12 Q. I'm asking you based upon your tends not to fragment the polymer, and that 13 knowledge as a biochemist, your knowledge of 13 releases additives so we can see additives 14 polypropylene, and your knowledge of the 14 without being overwhelmed by polymer fragments. 15 chemical structure, and the way that you've 15 One of the disadvantages of a PYMS by described the environmental stress cracking as 16 itself is that when you burn the polymer, in 16 17 we've been through it, isn't it more logical to this case polypropylene, you get a massive 17 18 conclude that environmental stress cracking 18 amount of polypropylene fragment ions which 19 19 would occur along the grain or the extrusion tends to overwhelm the ability of a detector to 20 lines as opposed to perpendicular to those 20 sense sometimes certain ions, like the 21 21 antioxidants, like Santonox, at least at the lines? 22 A. If you wanted -- if you picture long 22 levels that we want to detect it at. chains going this way of polymer, and then you 23 23 Q. As I understand your report and your 24 bent it this way, then it's going to tend to 24 earlier discussion, you used the PYMS analytical 25 25 crack here because those chains are going to technique to determine the extent to which

27 (Pages 102 to 105)

	Page 106		Page 108
1	additives in the Ethicon polypropylene mesh are	1	Q. Why not?
2	present?	2	A. We didn't think it would have any
3	A. That's right. I mean that's one of	3	effect on the results.
4	two. We use the LCMS as well.	4	Q. Why?
5	Q. Start with this one. Tell me how you	5	A. It's not an extracting solvent. It's
6	do that.	6	going to dissolve polypropylene, so it's not
7	A. How you determine	7	going to have any rapid effect on an extraction.
8	Q. Right.	8	Q. Why do you say that?
9	A. You well, you would first, if	9	A. Well, the polypropylene is solid. It
10	you're looking for Santonox R, you would shoot a	10	doesn't leach out additives quickly unless you
11	standard of Santonox R, and then you would look	11	put it in proper solvent extraction methods. Or
12	for the ions that you get. Santonox R gives	12	this case it was simply there, we didn't do an
13	ions at 358 and 343 atomic mass units, so you	13	extraction method, that's the LCMS, we just
14	would plot those ions and look at them as shown	14	simply put it in the sample holder and shoot it.
15	on figure well, the ions aren't shown in	15	Q. Have you analyzed the extent to which
16	Figure 82, but the chromatogram is.	16	formaldehyde is an oxidant?
17	Q. Let's back up a minute.	17	A. No.
18	When you're doing this test, do you	18	Q. And to the extent formaldehyde is an
19	test both the explants and the controls?	19	oxidant, you'd expect formalin to be an oxidant,
20	A. Absolutely.	20	wouldn't you?
21	Q. And why do you do that?	21	A. Right.
22	A. Because you want to look for	22	Q. To the extent that formalin is an
23	differences again. First of all, we want to be	23	oxidant, it would be appropriate to test the
24	sure that the pristine has it in it, and it did.	24	polypropylene pristine samples in formalin as a
25	And then we want to see whether or not the	25	part of your PYMS analysis, wouldn't it?
	Page 107		Page 109
1	explants have it in it.	1	A. It certainly could be done, but we
2	Q. Okay. Did you test the formalin	2	didn't do it.
3	controls as a part of the PYMS test?	3	Q. Because if you found that the
4	(Witness reviewing document.)	4	antioxidants were substantially reduced in the
5	A. It's not shown here. I'm going to	5	formalin control sample, that would impact your
6	have to go in the original data. A lot of the	6	opinions, wouldn't it?
7	stuff that was in the original data is not in	7	A. Yes.
8	this part.	8	Q. Why?
9	MR. ANDERSON: Go to the original	9	A. Well, then we would imply that the
10	data.	10	formalin extracted the polypropylene additives
11	MR. THOMAS: Is that all data that's	11	out.
12	been produced to us already?	12	Q. Have you analyzed at all in connection
13	A. It's all here, except you've got it on	13	with your work in this case the extent to which
14	dual sided. It's all here. So I have twice as	14	formalin will extract the antioxidants from the
15	much paper.	15	polypropylene mesh used in the TVT device?
16	BY MR. THOMAS:	16	A. We didn't do any work with formalin,
17	Q. While you look for that, I'm going to	17	so no.
18	go to the restroom.	18	Q. So what your findings in the PYMS
19	(Pause.)	19	section of the report show is only the pristine
20	A. Repeat the question. I'm sorry. I	20	mesh compared to the explanted mesh treated in
21	think I've got pretty close.	21	formalin?
22	BY MR. THOMAS:	22	A. That's correct.
	DI MR. INOMAS.		11. That's correct.
23	Q. Did you test the formalin control as a	23	Q. Now, the next step you take in the

28 (Pages 106 to 109)

1 Q. That's on Page 84 of your report. 2 A. Got it. 3 Q. And in this work, you did testing on 4 the control samples, didn't you? 5 A. Yes. 6 Q. And you did test work on the formalin 6 control samples, didn't you? 8 A. Yes. 9 Q. Turn to Page 96, please, of your 10 report. Table 19. 11 A. 19 starts on Page 95, just so you 12 know. 13 Q. Thank you. Take your time and look at 14 both of them if you want to, both pages. 15 A. Alon 16 — that's overlay of peaks of 16 wate the 357 ion that shows up, so we tune 16 the instrument to see, or to record only the 357 ion, which is specific to Santonox R, ignoring 18 all the other impurities, anything else that 19 might also be co-eluting. So it makes the 10 method specific. 10 Q. Thank you. Take your time and look at 11 both of them if you want to, both pages. 12 A. Rhe liquid is put in from a column 13 O. Thank you. Take your time and look at 14 both of them if you want to, both pages. 15 A. Alon 16 — that's overlay of peaks of 16 Mantonax R loops at 11.6 minutes about. 16 And extracted ion simply means we know 17 we have the 357 ion that shows up, so we tune 18 the instrument to see, or to record only the 357 ion, which is specific to Santonox R is port 19 method specific. 10 Q. Thank you. Take your time and look at 10 when it seals be co-eluting. So it makes the 10 mitotal shows up, so we tune 11 the instrument to see, or to record only the 357 ion, which is specific to Santonox R so we tune 14 the instrument to see, or to record only the 357 ion, which is specific to Santonox R Santonox R is port in time the instrument to see, or to record only the 357 ion, which is specific to Santonox R is port in minutes about. 14 the various is port in the specific in provide and into a mist, and a wild the detector and made into a mist, and a wild the detector and made into a mist, and a wild the detector and made into a mist, and a wild the detector and made into a mist, and a wild the detector and made into a mist, and a wild the detector and made into a mist, and a wild the detec		Page 110		Page 112
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A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak mean? A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? A. That's correct. Q. Okay. So what does the chart on Page amount of Santonox R, correct? A. That's correct. Q. The ranges in your control samples are extracted ion chromatograms, and you have all	2 3 4 5 6 7 8	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it	2 3 4 5 6 7 8	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that
12oxidation.12area is 315,246?13Q. All right. So on the left you have13A. Correct.14the numbers of your samples, correct?14Q. And you compare that to your control15A. Yes.15sample, 3398135, of 2,324,899, that's your16Q. And on the right you have the peak16pristine control sample?17area of Santonox R. What does the peak area17A. That's pristine control. There's some18wariability there.19A. It's just we're plotting you can19Q. And you'd conclude from that that the20see the photograph here of the peaks for20explant sample has a substantially diminished21Santonox R right above it, retention time.21amount of Santonox R, correct?22Q. Okay. So what does the chart on Page22A. That's correct.2395 represent above this table, the LCMS23Q. The ranges in your control samples are24extracted ion chromatograms, and you have all24as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental	2 3 4 5 6 7 8 9	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct?
Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? Q. Okay. So what does the chart on Page Yes a pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? A. That's correct. Q. Okay. So what does the chart on Page Yes a pristine control sample amount of Santonox R amount of Santonox R, correct? A. That's correct. Q. The ranges in your control samples are as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct?	2 3 4 5 6 7 8 9	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct.
the numbers of your samples, correct? 14 Q. And you compare that to your control 15 A. Yes. 16 Q. And on the right you have the peak 17 area of Santonox R. What does the peak area 18 mean? 19 A. It's just we're plotting you can 20 see the photograph here of the peaks for 21 Santonox R right above it, retention time. 22 Q. Okay. So what does the chart on Page 23 95 represent above this table, the LCMS 24 extracted ion chromatograms, and you have all 25 sample, 3398135, of 2,324,899, that's your 26 pristine control sample? 27 A. That's pristine control. There's some 28 variability there. 29 Q. And you'd conclude from that that the 20 explant sample has a substantially diminished 21 amount of Santonox R, correct? 22 A. That's correct. 23 Q. The ranges in your control samples are 24 as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to	2 3 4 5 6 7 8 9 10	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak
A. Yes. Q. And on the right you have the peak area of Santonox R. What does the peak area mean? A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time. Q. Okay. So what does the chart on Page extracted ion chromatograms, and you have all sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? A. That's correct. Q. The ranges in your control samples are as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10 11 12	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation.	2 3 4 5 6 7 8 9 10 11	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246?
Q. And on the right you have the peak area of Santonox R. What does the peak area mean? A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time. Q. Okay. So what does the chart on Page extracted ion chromatograms, and you have all pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? A. That's correct. Q. The ranges in your control samples are as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10 11 12 13	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have	2 3 4 5 6 7 8 9 10 11 12	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct.
area of Santonox R. What does the peak area mean? A. That's pristine control. There's some variability there. A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time. Q. Okay. So what does the chart on Page Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? A. That's pristine control. There's some variability there. 20 explant sample has a substantially diminished amount of Santonox R, correct? A. That's correct. 21 A. That's pristine control. There's some variability there. 22 explant sample has a substantially diminished 23 amount of Santonox R, correct? A. That's correct. 24 Page 14 A. That's pristine control. There's some variability there. 25 explant sample has a substantially diminished 26 amount of Santonox R, correct? A. That's correct. 27 Q. The ranges in your control samples are 28 extracted ion chromatograms, and you have all	2 3 4 5 6 7 8 9 10 11 12 13 14	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct?	2 3 4 5 6 7 8 9 10 11 12 13	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control
18 mean? 19 A. It's just we're plotting you can 20 see the photograph here of the peaks for 21 Santonox R right above it, retention time. 22 Q. Okay. So what does the chart on Page 23 95 represent above this table, the LCMS 24 extracted ion chromatograms, and you have all 25 Q. And you'd conclude from that that the 26 explant sample has a substantially diminished 27 amount of Santonox R, correct? 28 A. That's correct. 29 Q. The ranges in your control samples are 20 as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your
A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time. Q. Okay. So what does the chart on Page Solution of Santonox R, correct? A. That's correct. Q. The ranges in your control samples are extracted ion chromatograms, and you have all Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? A. That's correct. Q. The ranges in your control samples are as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample?
20 see the photograph here of the peaks for 21 Santonox R right above it, retention time. 22 Q. Okay. So what does the chart on Page 23 95 represent above this table, the LCMS 24 extracted ion chromatograms, and you have all 20 explant sample has a substantially diminished 21 amount of Santonox R, correct? 22 A. That's correct. 23 Q. The ranges in your control samples are 24 as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak area of Santonox R. What does the peak area	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some
21 Santonox R right above it, retention time. 22 Q. Okay. So what does the chart on Page 23 95 represent above this table, the LCMS 24 extracted ion chromatograms, and you have all 25 amount of Santonox R, correct? 26 A. That's correct. 27 Q. The ranges in your control samples are 28 as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak area of Santonox R. What does the peak area mean?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there.
Q. Okay. So what does the chart on Page 3 95 represent above this table, the LCMS 4 extracted ion chromatograms, and you have all 5 Q. That's correct. Calculate A. That's correct. Calculate	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak area of Santonox R. What does the peak area mean? A. It's just we're plotting you can	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the
95 represent above this table, the LCMS 24 extracted ion chromatograms, and you have all 25 Q. The ranges in your control samples are as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak area of Santonox R. What does the peak area mean? A. It's just we're plotting you can see the photograph here of the peaks for	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished
extracted ion chromatograms, and you have all 24 as high as 5,418,177, and as low as 2 thousand	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak area of Santonox R. What does the peak area mean? A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct?
	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak area of Santonox R. What does the peak area mean? A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time. Q. Okay. So what does the chart on Page	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? A. That's correct.
	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. That's correct. Q. And the Santonox R is put in the mesh to protect against the oxidation that you're critical of in this mesh? A. Yes. Q. And it's your opinion that the Santonox R leaches out of the mesh, making it more vulnerable to oxidation and environmental stress cracking, correct? A. Making it, yeah, more susceptible to oxidation. Q. All right. So on the left you have the numbers of your samples, correct? A. Yes. Q. And on the right you have the peak area of Santonox R. What does the peak area mean? A. It's just we're plotting you can see the photograph here of the peaks for Santonox R right above it, retention time. Q. Okay. So what does the chart on Page 95 represent above this table, the LCMS	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. What does peak area mean that's reported in Table 19? A. Just integrate the area under the curve that's observed. Q. Then you compare the peak area that you found for the explant samples against the control samples to determine the extent to which the Santonox R has been reduced, is that correct? A. That's correct. Q. So, for example, in 13674, the peak area is 315,246? A. Correct. Q. And you compare that to your control sample, 3398135, of 2,324,899, that's your pristine control sample? A. That's pristine control. There's some variability there. Q. And you'd conclude from that that the explant sample has a substantially diminished amount of Santonox R, correct? A. That's correct. Q. The ranges in your control samples are

29 (Pages 110 to 113)

	Page 114		Page 116
1	MR. ANDERSON: Objection. Million.	1	A. That's the only explanation I can
2	MR. THOMAS: Thank you.	2	think of.
3	A. Millions, yes. But you're right.	3	Q. But you didn't study the extent to
4	BY MR. THOMAS:	4	which formalin impacts the antioxidants in the
5	Q. If you look at the formalin treated	5	mesh as a part of your analysis in this case,
6	control samples on Page 96 at Table 19, the	6	correct?
7	formalin treated control samples have less	7	MR. ANDERSON: Objection as to form.
8	Santonox R than the regular control samples,	8	Go ahead.
9	don't they?	9	A. No.
10	A. They do.	10	BY MR. THOMAS:
11	Q. Did you make any analysis to determine	11	Q. It's correct that you did not?
12	why?	12	A. I did not.
13	A. I would assume that that you have	13	Q. Thank you.
14	to assume by the data that that means that	14	Now, if you look at the same table,
15	the because it was the same 3405405 was	15	Table 19, you look at lot 3422128.
16	analyzed before and after the formalin	16	A. Where are we now?
17	treatment, so formalin treatment extracted some	17	Q. Under "Control Samples," same table,
18	of the antioxidant.	18	Table 19 on Page 96.
19	Q. Let's look at that, because the	19	A. Okay.
20	formalin treated control sample is 3405405, and	20	Q. You see that there's a control sample
21	it says 2,216,989.	21	which is lot number 3422128. Do you see that?
22	A. Right.	22	And a value of 4,550,748. Do you see that?
23	Q. If you go up to the control sample	23	A. I see it.
24	with the same lot number, that means it's the	24	Q. And then there is another a
25	same material, just with no formalin, correct?	25	duplicate of that same control sample also
	Page 115		Page 117
1	A. That's right.	1	tested. Do you see that?
2	Q. And the peak area there is 4,012,675,	2	A. Yes.
3	correct?	3	Q. And for that duplicate, that's the
4	A. Yes.	4	same piece of mesh, isn't it?
5	Q. Can't you conclude from that that the	5	A. It's a different sample, but it would
6	formalin is extracting the Santonox R from this	6	be the same piece of mesh, yes.
7	mesh sample?	7	Q. And that's a duplicate of the same
8	A. You can. Not completely, but it is.	8	test with the 4,550,748 test, right?
9	Q. Okay. Is there any other explanation	9	A. Right.
10	for what's going on there?	10	Q. And the value that you get for the
11	A. I don't think so.	11	duplicate sample is 5,418,177, correct?
12	Q. Now, if you look at the other formalin	12	A. Correct.
13	control sample, lot number 3422128, it shows a	13	Q. Do you have any explanation for the
14	peak area of 1,019,604. And if you compare that	14	difference in peak areas between these two, what
15	to the same control sample without formalin, the	15	should be duplicate samples?
1 1 /	number 10 /L SSUL L/LX correct?	16	A. It should be duplicate samples, but
16	number is 4,550,748, correct?	1	
17	A. Yes, you're right.	17	it's a different it's actually a different
17 18	A. Yes, you're right.Q. And it's more than four times the	18	it's a different it's actually a different region in the mesh. So it could be due to the
17 18 19	A. Yes, you're right.Q. And it's more than four times the amount of Santonox in the pristine sample than	18 19	it's a different it's actually a different region in the mesh. So it could be due to the fact that the antioxidant is not completely
17 18 19 20	A. Yes, you're right. Q. And it's more than four times the amount of Santonox in the pristine sample than there is in the formalin sample, correct?	18 19 20	it's a different it's actually a different region in the mesh. So it could be due to the fact that the antioxidant is not completely evenly distributed in the mesh, so there's
17 18 19 20 21	 A. Yes, you're right. Q. And it's more than four times the amount of Santonox in the pristine sample than there is in the formalin sample, correct? A. Correct. 	18 19 20 21	it's a different it's actually a different region in the mesh. So it could be due to the fact that the antioxidant is not completely evenly distributed in the mesh, so there's regions of higher and lower concentration.
17 18 19 20 21 22	 A. Yes, you're right. Q. And it's more than four times the amount of Santonox in the pristine sample than there is in the formalin sample, correct? A. Correct. Q. And you have to conclude that the 	18 19 20 21 22	it's a different it's actually a different region in the mesh. So it could be due to the fact that the antioxidant is not completely evenly distributed in the mesh, so there's regions of higher and lower concentration. Q. Do you know?
17 18 19 20 21 22 23	 A. Yes, you're right. Q. And it's more than four times the amount of Santonox in the pristine sample than there is in the formalin sample, correct? A. Correct. Q. And you have to conclude that the reason why there's less in the formalin treated 	18 19 20 21 22 23	it's a different it's actually a different region in the mesh. So it could be due to the fact that the antioxidant is not completely evenly distributed in the mesh, so there's regions of higher and lower concentration. Q. Do you know? A. No. I'd have to run a series of
17 18 19 20 21 22	 A. Yes, you're right. Q. And it's more than four times the amount of Santonox in the pristine sample than there is in the formalin sample, correct? A. Correct. Q. And you have to conclude that the 	18 19 20 21 22	it's a different it's actually a different region in the mesh. So it could be due to the fact that the antioxidant is not completely evenly distributed in the mesh, so there's regions of higher and lower concentration. Q. Do you know?

30 (Pages 114 to 117)

	Page 118		Page 120
1	and the duplicate control sample of the pristine	1	Q. You had samples in the formalin
2	mesh tested almost a million DAs apart, does	2	control for how long? 48 hours at 60 degrees
3	that cause you any concern at all?	3	centigrade?
4	A. Well, if it's different it's	4	A. Yes.
5	different. I can't control that.	5	Q. Did you make any effort to correlate
6	Q. Okay. Does the fact that the control	6	the aging by that amount to the samples that are
7	sample lot 3422128, the duplicate, shows a peak	7	contained in Table 19 to determine whether
8	area of 5,418,177, and the formalin treated	8	they're equivalent?
9	control sample for the same piece of mesh is	9	A. No.
10	less than 20 percent of that value, does that	10	Q. It would be appropriate in any
11		11	
12	have any concern cause you any concern about	12	scientific analysis to make sure that when
13	the opinions you have in the case?	13	you're comparing formalin exposure, you want
$\frac{13}{14}$	A. Where are we here? Sorry.	14	them to be equal to make sure that they reflect
	Q. Okay. We're at Table 19, Page 96.	l .	accurate values?
15	You have	15	A. Well, the only way to do that, it
16	A. Duplicate.	16	would be rather impossible in this case, it
17	Q. You have your duplicate lot for	17	would have had to have been implanted in tissue,
18	3422128, the value is 5,418,177. And the same	18	and had to have been implanted and stored in the
19	piece of mesh treated with formalin is less than	19	formaldehyde for you know, like we'd have to
20	20 percent the concentration of Santonox R as	20	take controls. I don't know how we'd put
21	you found in your pristine sample.	21	controls in tissue. There's all kinds of
22	A. Yes. It looks like formalin is	22	possible requirements to do that technically.
23	extracting it, as we said before.	23	Q. Is it fair to conclude based on the
24	Q. Why didn't you note that in your	24	data in your report, at least with respect to
25	report?	25	lot number 3422128, the duplicate sample, and
	Page 119		Page 121
1	Page 119 MR. ANDERSON: Objection.	1	Page 121 the formalin control sample, that the formalin
1 2		1 2	
	MR. ANDERSON: Objection.	l .	the formalin control sample, that the formalin
2	MR. ANDERSON: Objection. A. I did. It's in the table.	2	the formalin control sample, that the formalin is responsible for extracting over 80 percent of
2	MR. ANDERSON: Objection. A. I did. It's in the table. BY MR. THOMAS:	2 3	the formalin control sample, that the formalin is responsible for extracting over 80 percent of the Santonox R?
2 3 4	MR. ANDERSON: Objection. A. I did. It's in the table. BY MR. THOMAS: Q. Why didn't you discuss it in your	2 3 4	the formalin control sample, that the formalin is responsible for extracting over 80 percent of the Santonox R? A. Given the spread on the data, it's
2 3 4 5	MR. ANDERSON: Objection. A. I did. It's in the table. BY MR. THOMAS: Q. Why didn't you discuss it in your report?	2 3 4 5	the formalin control sample, that the formalin is responsible for extracting over 80 percent of the Santonox R? A. Given the spread on the data, it's certainly it is suggestive of that. But
2 3 4 5 6	MR. ANDERSON: Objection. A. I did. It's in the table. BY MR. THOMAS: Q. Why didn't you discuss it in your report? A. Well, there's normally experimental	2 3 4 5 6	the formalin control sample, that the formalin is responsible for extracting over 80 percent of the Santonox R? A. Given the spread on the data, it's certainly it is suggestive of that. But again, it could be 40 percent or 60 percent or
2 3 4 5 6 7	MR. ANDERSON: Objection. A. I did. It's in the table. BY MR. THOMAS: Q. Why didn't you discuss it in your report? A. Well, there's normally experimental error, I can't it's possible that this	2 3 4 5 6 7	the formalin control sample, that the formalin is responsible for extracting over 80 percent of the Santonox R? A. Given the spread on the data, it's certainly it is suggestive of that. But again, it could be 40 percent or 60 percent or 50 percent because it could be a different
2 3 4 5 6 7 8	MR. ANDERSON: Objection. A. I did. It's in the table. BY MR. THOMAS: Q. Why didn't you discuss it in your report? A. Well, there's normally experimental error, I can't it's possible that this million is there because instead of 2 million	2 3 4 5 6 7 8	the formalin control sample, that the formalin is responsible for extracting over 80 percent of the Santonox R? A. Given the spread on the data, it's certainly it is suggestive of that. But again, it could be 40 percent or 60 percent or 50 percent because it could be a different region of the fiber itself. We have normal
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31 (Pages 118 to 121)

	Page 122		Page 124
1	A. That's correct.	1	A. It did not remove at all. It didn't
2	Q. And you could have tested other	2	remove it to the same levels as seen in the
3	regions in the mesh to determine the extent to	3	explants.
4	which the antioxidants varied across the mesh,	4	BY MR. THOMAS:
5	correct?	5	Q. But it's true to a reasonable degree
6	A. Theoretically. We did a huge amount	6	of scientific certainty as reflected by your
7	of work to begin with, so it's all a relative	7	data that the formalin removed more than
8	what you're capable of doing in the required	8	80 percent of the antioxidants as expressed in
9	time and all the rest of it, so it's just a	9	that data?
10	judgment call.	10	MR. ANDERSON: Objection.
11	Q. The reason why you did testing was to	11	A. I have to look at the numbers.
12	have the data points upon which you could	12	(Witness reviewing document.)
13	predicate your opinions?	13	A. The samples that's true. And in
14	A. That's right.	14	the samples as received, we had like 1, 2 or
15	Q. And these are the only data points	15	3 percent left, not 80 percent. We only had
16	that you have upon which to predicate your	16	so it had 97, 98, 99 percent removed in the
17	opinions?	17	explants we received. Still greater.
18	A. That's right.	18	BY MR. THOMAS:
19	MR. ANDERSON: Well, objection to	19	Q. But you don't know how long those
20	form.	20	explants were exposed to formalin, do you?
21	A. Not the only, but it's one of.	21	A. No, I do not.
22	BY MR. THOMAS:	22	Q. And the length of time those explants
23	Q. For this issue, for the LCMS data?	23	may have been exposed to formalin would impact
24	A. For Santonox R for the LCMS data, for	24	the extent to which the formalin extracted the
25	the lauryl thiodipropionate, for example.	25	antioxidants, correct?
	Page 123		Page 125
1	Q. As a scientist who works in	1	A. Presumably.
2	biochemistry and uses this type equipment, does	2	Q. Well, absent any testing showing you
3	the variability in the data in Table 19 on	3	otherwise, that would be the logical conclusion
4	Page 96 suggest to you the need to do additional	4	from this data, wouldn't it?
5	testing to confirm the extent to which formalin	5	A. Yes.
6	was involved in the extraction of the	6	MR. THOMAS: Let's eat.
7	antioxidants?	7	(Whereupon, a luncheon recess was
8	A. That would be a good idea, sure.	8	taken at 12:15 p.m.)
9	Q. Because the data as expressed here is	9	takon at 12.15 p.m.)
10	not reliable, is it?	10	
11	A. Well, that's a relative term. I think	11	
12	we certainly got nowhere near the levels seen in	12	
13	the explants.	13	
14	Q. Is it still your opinion that to a	14	
15	reasonable degree of scientific certainty that	15	
16	formalin has no impact on the Santonox R in the	16	
17	mesh as implanted in a person?	17	
18	A. As implanted in a person, I don't	18	
19	Q. Bad question.	19	
20	Is it still your opinion to a	20	
21	reasonable degree of scientific certainty that	21	
22	the formalin had no impact on the measurement of	22	
23	antioxidants in the meshes analyzed by you, the	23	
24	explants?	24	
25	MR. ANDERSON: Objection.	25	

32 (Pages 122 to 125)

	Page 126		Page 128
1	AFTERNOON SESSION	1	case has been done since the testing work
2	1:12 O'CLOCK P.M.	2	itself has been done since September. Does that
3	1.12 O CLOCK 1.141.	3	seem about right?
4	BY MR. THOMAS:	4	A. Yes.
5	Q. Let's spend a little time with your	5	Q. Okay. In Table 2 on Page 15 there's
6	report, Dr. Jordi.	6	identification of the sample, weight, fibers.
7	A. Okay.	7	Is that molecular what is the weight for
8	Q. The report in the Lewis case. Let's	8	that? What does that mean?
9	- 1	9	A. That was the amount of fibers that
10	go back to Page 16 again.	10	
11	Table 2 on Page 16, it begins on Table		were able to be extracted. So when you look at
12	on Page 15, I guess, to be fair.	11	the picture of the on Page 16 at the bottom
	A. Yes.	12	left, those fibers after they were removed from
13	Q. Table 2 represents what?	13	tissue were weighed.
14	A. Table 2 represents a grid of the tests	14	Q. Okay. Is there any weight of a tissue
15	that were run.	15	that you have?
16	Q. There is a number of sample	16	A. No. We had no plans for analysis of
17	identification numbers beginning with 13400 that	17	the tissue.
18	run to 13421. I assume you did all of those	18	Q. Did you retain the mesh fibers that
19	tests at once, or about the same time?	19	are in Figure 2?
20	A. About the same time. We received the	20	A. Well, we would have if there were any
21	Lewis case a little bit later, so it was run a	21	to maintain. There may be tidbits of a couple
22	little bit later.	22	of them. But with all the testing that was
23	Q. Is it your practice to number the	23	done, we were extremely sample constrained.
24	testing that you do in your labs sequentially?	24	Q. How about the tissue samples, did you
25	A. Yes.	25	retain any of the tissue samples?
	Page 127		Page 129
1	Q. Is there any significance to the	1	A. No. We had no further use for the
2	numbers, other than the time that you do it?	2	tissue.
3	A. I don't believe so. It's just the	3	Q. Under the 13674, you understand that
4	standard SOP numbering.	4	to be the Carolyn Lewis sample?
5	Q. Okay. When did you do the testing for	5	A. Yes, I do.
6	13400 to 13421, over what period of time. I	6	Q. There's no weight taken there. Do you
7	don't think you'll find it in your report. I've	7	know why?
8	got the bills here if that helps.	8	A. It was an oversight. It's
9	MR. ANDERSON: Lab notebooks would	9	7.62 milligrams. It's in the book.
10	help, too.	10	Q. Okay. So it's in your lab notebook,
11	A. Lab notebooks would probably be	11	but never made it to your report?
12	better.	12	A. That was a glitch. It should have
13	BY MR. THOMAS:	13	made it to the report. It didn't make it to the
14	Q. Okay.	14	report.
15	(Witness reviewing documents.)	15	Q. What's the significance of
16	A. Looks like about the start was 9/9.	16	A. It's 7.62 if you want to write it in
17	MR. ANDERSON: Look at your lab	17	so you've got the exact number.
	· · · · · · · · · · · · · · · · · · ·	18	Q. What is the significance of that
×	notehooks instead of saying "about "		
18 19	notebooks instead of saying "about." THE WITNESS: I did look at the lab		number to your analysis?
19	THE WITNESS: I did look at the lab	19	number to your analysis?
19 20	THE WITNESS: I did look at the lab notebook there.	19 20	A. The milligrams?
19 20 21	THE WITNESS: I did look at the lab notebook there. These were all these samples that are	19 20 21	A. The milligrams?Q. Yes, the weight of the fibers that you
19 20 21 22	THE WITNESS: I did look at the lab notebook there. These were all these samples that are in that grid, so 9/11, 9/13.	19 20 21 22	A. The milligrams?Q. Yes, the weight of the fibers that you receive.
19 20 21 22 23	THE WITNESS: I did look at the lab notebook there. These were all these samples that are in that grid, so 9/11, 9/13. BY MR. THOMAS:	19 20 21 22 23	A. The milligrams?Q. Yes, the weight of the fibers that you receive.A. It's just a fact of what we got.
19 20 21 22	THE WITNESS: I did look at the lab notebook there. These were all these samples that are in that grid, so 9/11, 9/13.	19 20 21 22	A. The milligrams?Q. Yes, the weight of the fibers that you receive.

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Page 130 Page 132 1 1 sample analysis chart, it lists the tests done background in polymer science, this level of 2 2 on each sample, correct? degradation will have a strong impact on fiber 3 A. Correct. 3 mechanical properties, including stiffness, 4 4 Q. You didn't do all of the tests on all elasticity, and resistance to break." 5 5 What level of degradation are you the samples? 6 6 A. Correct. describing in that sentence? 7 7 Q. Why? A. We're describing the very obvious A. Some cases there just wasn't enough 8 8 cracking seen in the SEM photographs. 9 sample to do them all. And other cases we --9 Q. Okay. So the level that you're 10 like we ran SEM and optical microscopy on all 10 describing there relates solely to what you the samples. SEM-EDX, once we've seen increased 11 observed in the SEM photographs, images? 11 12 oxygen six times, we didn't feel it was 12 A. At this point, yes. 13 13 necessary to run them all. It's already a huge Q. All right. "Will have a strong impact 14 on fiber mechanical properties." What does that 14 report. The volume of work was so great that we 15 made choices when we had acquired what we 15 term mean to you? How much is strong? 16 16 considered a significant level of work. Once I A. Well, we weren't able to run physical 17 prove something six times, I don't need to prove 17 testing that we normally would run, because we 18 18 didn't have enough material, but we could feel, it seven, eight, nine, ten times. Part of it 19 was lack of sample, part of it was we'd run 19 one way is to feel it. The material explanted 20 enough to be consistent to show the point of the 20 material had a much more rigid feeling to it, I 21 21 various analyses. guess the best word is rigid, rigid feeling to 22 22 Q. Did the expense of the test have it than the controls. 23 23 anything to do with it, the expense of each of Q. Okay. 24 the tests? 24 A. It was very obvious. 25 A. I'm sure that wasn't the overriding --25 Q. Is that the only information that you Page 131 Page 133 1 that wasn't the overriding thing. 1 have that the level of degradation that you 2 Q. Did you determine which fibers to test 2 observed would have a strong impact on fiber 3 with which test, or were you directed in that 3 mechanical properties? 4 regard? 4 A. No. If I looked at the actual flaking 5 A. No. We discussed that, and we just 5 and the cracking and so on and so forth, that's б made a choice of statistical significance. б got to have a massive effect. It's a large --Q. Who made that decision? 7 7 it covers the entire region of some of the 8 8 A. Well, my son Mark and I. fibers. 9 Q. Okay. What considerations did you 9 Q. Okay. You call it strong, you said have in determining, for example, to do all of 10 massive. What does that mean? 10 the OM and SEMs, but only some of the SEM-EDX? 11 A. Well, the best way I can show it is 11 12 12 MR. ANDERSON: Objection. Asked and with a picture. answered. 13 Q. Okay. 13 A. Do you want to see one? 14 Go ahead. 14 Q. You've showed them to me, and I've 15 A. We just didn't feel it was -- we had 15 showed the point, and we just thought we had seen them. 16 16 done enough work. And we had a huge work 17 17 In terms of quantifying, placing a 18 product to begin with. 18 number on the impact on the mechanical BY MR. THOMAS: 19 19 properties, you're not able to do that, is that 20 Q. Okay. Is there a reason -- strike 20 fair? 21 21 A. I think you could certainly say it was that. 22 Let's go to Page 19. Page 19 in the 22 great -- very greatly cracked or moderately 23 middle of the page, it reads this. "It is my 23 cracked, something like that in general. 24 opinion to a reasonable degree of scientific 24 Putting a number score on it would be difficult, 25 25 certainty based upon my experience and my yes. But it certainly is not hard to look at a

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Page 134 Page 136 1 fiber mesh." 1 sample that's grossly cracked and see that it's 2 2 grossly cracked. There's nothing in there that I saw 3 Q. You say that it's "going to have a 3 that suggested that you compared the formalin 4 4 strong impact on fiber mechanical properties, control samples. Do you recall testing the 5 5 including stiffness." formalin control samples in the same way that 6 6 What impact will this degradation have you tested the control samples and the explants? 7 7 A. It's not specifically mentioned, but on stiffness? 8 8 A. Cracking, the cracking to me is we felt them. 9 9 indicative of some -- is a form of degradation, Q. Okay. And it's your recollection and 10 at least it's a result of the chemical 10 testimony that the explanted samples felt 11 11 degradation, results in a physical splintering stiffer than the control samples? 12 that we see. So that when it's largely cracked, 12 A. Most definitely. 13 Q. And did you arrive at any conclusions 13 that also implies that the material underneath 14 about what caused that stiffness? 14 it is probably cracking, too. And I prove that 15 by showing the SEM-EDX and showing the increased 15 A. At the time it was done, we hadn't 16 16 oxygen levels in the level underneath the done the other testing, so I had no reason or 17 cracks, that's the next layer that will crack. 17 cause. After all the work that's done and 18 18 Q. Thank you, Doctor. reported here in this report, the infrared 19 My question is; what level of --19 showed oxidation, the SEM-EDX shows oxidation, 20 20 the lack of antioxidants would suggest strike that. 21 21 What amount of stiffness is impacted susceptibility to oxidation, and so on. 22 22 Q. Okay. The sentence also references by the level of degradation that you observed in 23 23 the SEM images? What's the -- how can you elasticity. Was the elasticity also something 24 quantify the level of stiffness? 24 that you observed in the handling of the mesh? 25 A. I can just feel it. I'm sorry, I 25 A. Right. If you bent the original --Page 135 Page 137 1 can't give you a number. 1 the pristine mesh it would come -- pop right 2 Q. And just so it's clear, the only thing 2 back to shape. And the other, you had to apply 3 that you have to go on about the stiffness is 3 more force to get it bent, and it would come 4 holding the explant in your hands? 4 back and sometimes would stay partially bent, or 5 5 A. In the gloved hands. sometimes would crack. 6 б Q. Okay. Q. Is it the handling of the mesh the A. And -- yes. 7 7 only basis for your opinion that the explanted 8 8 Q. Comparing it to -mesh was less elastic than the control? 9 A. To the control. 9 A. As a comment here, yes, because that's Q. -- the control. 10 a point where we were running SEM. 10 11 Did you compare that to the formalin 11 Q. And likewise, with the resistance to control, or just the control? 12 12 break, did you observe that in your handling as 13 A. I think we felt them all. 13 well? A. That's right. 14 Q. I didn't see any reference in your 14 report to the formalin control. 15 15 Q. And is it fair to understand that it's Do you have a -- is it your practice 16 your handling of the explanted mesh as compared 16 when you test the formalin controls to reference 17 to the control mesh that's the basis for your 17 18 that in your report? 18 opinion that the explanted mesh had less A. Reference what in the report? 19 resistance to break than the control mesh? 19 20 Q. The fact that you did it. 20 A. Yes. The control mesh never broke. If you go on Page 17, it's where you 21 21 Q. Did you ever investigate any talk about handling it. Page 17 says "It was 22 22 alternative potential causes to more stiffness, 23 noted during sample preparation that a readily 23 less elasticity, or more resistance to break? 24 apparent difference in fiber stiffness existed 24 A. No. We were going after chemical 25 25 between the control samples and the explanted analysis of the polypropylene and the

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Page 138 Page 140 1 1 differences, if any. Q. How do you know that's the way it was 2 2 Q. Did you ever consider any other inside the body? 3 chemical contributions to increased stiffness --3 A. Well, it was in the tissue when it 4 4 strike that. came, and we didn't take it out of the tissue 5 5 when we sent it -- when we ran the SEM, so we Did you ever consider whether formalin 6 6 could contribute to increased stiffness, less didn't do anything different than it was in the 7 7 elasticity, or less resistance to break? body environmentally. We did that on purpose. 8 A. We felt it. The same, it felt the 8 Q. You didn't do anything differently, 9 9 same. but the doctors did something differently when 10 10 they removed the mesh, didn't they? Q. Did you consider that at the time? 11 11 A. If it had been different it would have A. Well, they took it out of the body, 12 12 been reported. The fact that it was a formalin yes. 13 13 treated control would be part of the control Q. What else did they do? 14 A. Put it in formalin. 14 package. 15 Q. Well, the formalin treated control 15 Q. Okay. Do you know what impact the 16 16 observations weren't even called out in your formalin has on the proteins and other -- strike 17 report, right? 17 A. That's right, they weren't. 18 18 Do you have any knowledge or 19 Q. Okay. Did you ever consider the 19 information about what formalin does to the 20 extent to which formalin and a chemical reaction 20 materials in the body that surround the mesh? with the proteins on the mesh could lead to an 21 MR. ANDERSON: Objection to form. 21 22 22 increased stiffness, a reduced elasticity, or a A. It will react with the tissue, but it 2.3 23 reduced resistance to break? will not react -- we ran controls in formalin 24 A. No. 24 here, and we showed it didn't change the SEM. 25 Q. Down in the middle of that paragraph 25 BY MR. THOMAS: Page 139 Page 141 you say "Sharp or protruding surfaces could 1 1 Q. But the ones you ran in formalin 2 result." 2 didn't have any tissue on them. 3 Do you have an opinion to a reasonable 3 MR. ANDERSON: Wait a minute, Dave, in 4 degree of scientific certainty that any sharp or 4 fairness let him finish his answer. 5 protruding surfaces resulted from any of these 5 MR. THOMAS: You're right. pieces of mesh? 6 б A. We ran formalin treated controls here 7 7 A. Where are we reading here? to see if it would do anything obvious to the Q. Right in the middle of that paragraph. 8 8 pristine. It did not. 9 MR. ANDERSON: Page 19. 9 BY MR. THOMAS: A. Oh, 17. All right. Which paragraph? 10 Q. But the formalin controls that you ran 10 MR. ANDERSON: You're on 18. He 11 11 didn't have any tissue on them. wanted 19. He's going to keep going through 12 A. That's correct. So what? 12 13 this paragraph, so here's where he is right now. 13 Q. And my question is whether you know 14 A. "Sharp protruding..." 14 whether formalin will react with the tissue on 15 (Witness reviewing document.) 15 the mesh so as to impact the appearance in the A. Okay. Question again, please? 16 SEM images. Do you know that? 16 17 BY MR. THOMAS: A. Absolutely not. It will react with 17 18 Q. Do you have an opinion to a reasonable 18 the tissue, absolutely. It's irrelevant. It's degree of scientific certainty that any sharp or 19 not going to react with the mesh. It will 19 20 protruding surfaces resulted on any of the mesh 20 react -- not react with the mesh in the tissue, 21 21 explants that you reviewed in vivo? it will react with the tissue which we removed, 22 MR. ANDERSON: Objection to form. 22 so it's no longer there when we did the testing. 23 A. We saw the sharp edges in the SEM 23 Q. Is it your testimony there was no --24 A. There was tissue on when the SEMs were 24 photos. BY MR. THOMAS: 25 25 run. We didn't want that removed because didn't

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Page 142 Page 144 1 1 want to in any way disturb the mesh in any way A. That was well understood in that we 2 2 had very little response. Because in that case, that we could possibly avoid, so we tried our 3 3 very best not to cause anything, any changes. unlike this case, we had a polymer in polylactic 4 4 So we ran the SEMs in the tissue, which we could and polyglycolic acid which degraded to lactic 5 5 acid and glycolic acid, both of which are normal 6 6 body chemicals that don't cause a tissue Q. What is your area of expertise that 7 7 allows you to give the opinion that "Prolene response of any consequence. 8 mesh in the TVT products degrades, cracks, and 8 Q. Was it your job to determine the 9 9 releases polypropylene particulates into the extent to which the jaw implant would integrate 10 surrounding tissue after implantation, causing 10 into the tissue? 11 an increased inflammatory response"? Are you 11 A. To observe it. 12 12 trained to give that opinion? Q. Was it your job to determine the 13 13 A. I certainly am. I'm a polymer adequacy of the design of the jaw implant to be 14 14 chemist, a biochemist, and we actually saw the accepted by the tissue? 15 shards, we saw how easily the shards came off, 15 A. Well, we worked as a team. There was 16 16 and then we actually took an infrared of it to a number of us. 17 show that they were polypropylene. So we 17 Q. But there were other people whose 18 18 actually did it and we saw it. primarily responsibility was to determine the 19 Q. That's not -- that's a good answer. I 19 extent to which the implant was compatible with 20 should have asked a better question. 20 existing tissue, wasn't it? 21 21 What's your training, education, and A. That work had been done prior, it had experience that allows you to give the opinion 22 22 been shown to be compatible. 23 that those pieces that you claim break off 23 Q. But that was not your job? 24 caused an increased inflammatory response? 24 A. No. 25 A. What's my basis? 25 Q. Somebody else did that work? Another Page 143 Page 145 1 Q. Yes. What's your training? expertise was required to make that finding, 2 A. I'm a biochemist. 2 correct? 3 Q. As a part -- have you analyzed the 3 A. Right. 4 effect of polymer degradation in humans prior to 4 Q. And so --5 this litigation? 5 A. But it's not unreasonable to observe 6 б A. I worked on bio-implantable polymers polypropylene shards coming off, which are 7 7 when I was in the Army at Walter Reed Army little knives. They're going to cut the tissue 8 8 Medical Center, polylactic acid, polyglycolic when they come off in it. You can see it under 9 acid copolymers. 9 microscope, and that's going to cause bleeding Q. Was your work there --10 and an inflammatory response. 10 11 MR. ANDERSON: He's not finished. 11 Q. How big are these shards you're 12 12 talking about? 13 A. We were replacing parts of jaws in 13 A. Well, let's go look at a picture. 14 animals with a goal of being able to replace a 14 We've got a scale on it. They vary. 15 blown off jaw on a soldier, put a piece of 15 Q. How big is that one? What page are implantable material in the jaw, and then we you on? 16 16 wanted the tissue to grow into it, so we put 17 17 A. 69. 18 things in the PLA-PG polymer so tissue would 18 Q. How big is it? 19 MR. ANDERSON: Which piece? There's 19 tend to grow in, and ultimately the jaw would be 20 replaced with new jaw, and it worked fairly 20 pieces all over the place. 21 21 MR. THOMAS: The piece he has well. 22 BY MR. THOMAS: 22 highlighted right there. 23 Q. Was it your job to determine the 23 MR. ANDERSON: Okay. 24 extent to which the implant would be accepted by 24 A. Well, the mesh itself is, what, 70, 25 25 existing tissue? 80 microns, so it's got to be -- this is a good

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	Page 146		Page 148
1	size piece, so it's probably 20 microns,	1	you draw a circle around what you've described
2	10 microns, 20 microns, depends on the piece.	2	as the polypropylene.
3	BY MR. THOMAS:	3	MR. ANDERSON: On his copy? Do you
4	Q. And it's your opinion that that cuts	4	want to put it on let's put it on the record
5	tissue?	5	copy.
6	A. Absolutely. If it's got sharp edges	6	MR. THOMAS: That's what I thought he
7	like this and you're moving around and	7	was looking at. I'm sorry.
8	exercising, it's got to drive it into	8	A. It would be the same page.
9	whatever	9	BY MR. THOMAS:
10	Q. What have you done to study the extent	10	Q. So we're on Page 42 of Exhibit 1.
11	to which a shard as depicted on the Page 69 is	11	A. Yes.
12	going to have any impact at all in terms of	12	MR. ANDERSON: You're going to write
13	inflammatory response in a human?	13	on this.
14	A. I leave that to the doctors, the	14	BY MR. THOMAS:
15	surgeons, and so on, and the doctors. I'm not	15	Q. So why don't you draw a circle around,
16	a I'm a biochemist and a polymer chemist.	16	if you don't mind, those areas
17	Q. Right. So the extent to which any of	17	A. Circle?
18	these edges that you've described, cracks that	18	MR. ANDERSON: Listen to him.
19	you've described, or platelets or shards that	19	BY MR. THOMAS:
20	you've described are going to have any health	20	Q. Outline the area that you believe is
21	impact on any patient is for somebody else to	21	polypropylene.
22	comment on, is that fair?	22	A. (Witness complies).
23	A. The doctors have to do that, yes.	23	I'm having a hard time writing
24	Q. Thank you.	24	exactly, but you give my drift.
25	Let's go to Page 42 of your report,	25	BY MR. THOMAS:
	Page 147		Page 149
1	please.	1	Q. Doesn't have to be exact.
2	A. Got it.	2	A. Looks like a crack there.
3	Q. I'm interested in the figure that's on	3	Q. Okay.
4	the lower half of the page. I guess it's Figure	4	A. Something on that order.
5	48.	5	Q. And so thank you for doing that.
6	Based on your work in this case, what	6	You've drawn in red the area inside of
7	does Figure 48 show?	l _	
0		7	which is the polypropylene. Does the area
8		8	
9	A. It shows a large this is atypical. It shows a large longitudinal crack in the		which is the polypropylene. Does the area
	A. It shows a large this is atypical.	8	which is the polypropylene. Does the area outside of that represent tissue or protein?
9	A. It shows a large this is atypical. It shows a large longitudinal crack in the	8 9	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so.
9 10	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears	8 9 10	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay.
9 10 11	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue.	8 9 10 11	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides
9 10 11 12	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that	8 9 10 11 12	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when
9 10 11 12 13	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that and I think of bark on a tree. And there's	8 9 10 11 12 13	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more tissue is more nebulous. Q. What is it about the polypropylene
9 10 11 12 13 14	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that and I think of bark on a tree. And there's areas on either side, and then an interior that	8 9 10 11 12 13 14	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more tissue is more nebulous.
9 10 11 12 13 14 15 16 17	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that and I think of bark on a tree. And there's areas on either side, and then an interior that I would think of as exposed wood on a tree and the rest would be the bark, and I'm trying to use it as kind of a descriptive thing.	8 9 10 11 12 13 14 15	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more tissue is more nebulous. Q. What is it about the polypropylene
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9 10 11 12 13 14 15 16 17 18	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that and I think of bark on a tree. And there's areas on either side, and then an interior that I would think of as exposed wood on a tree and the rest would be the bark, and I'm trying to use it as kind of a descriptive thing. Is the area surrounding the interior portion that's not going to make any sense at	8 9 10 11 12 13 14 15 16 17 18	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more tissue is more nebulous. Q. What is it about the polypropylene structure that causes it to crack in the manner you just described? MR. ANDERSON: Objection to form. Go ahead.
9 10 11 12 13 14 15 16 17 18 19 20	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that and I think of bark on a tree. And there's areas on either side, and then an interior that I would think of as exposed wood on a tree and the rest would be the bark, and I'm trying to use it as kind of a descriptive thing. Is the area surrounding the interior portion that's not going to make any sense at all on the record, I understand that. Are we	8 9 10 11 12 13 14 15 16 17 18 19 20	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more tissue is more nebulous. Q. What is it about the polypropylene structure that causes it to crack in the manner you just described? MR. ANDERSON: Objection to form. Go ahead. A. It's developed brittleness from lack
9 10 11 12 13 14 15 16 17 18 19 20 21	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that and I think of bark on a tree. And there's areas on either side, and then an interior that I would think of as exposed wood on a tree and the rest would be the bark, and I'm trying to use it as kind of a descriptive thing. Is the area surrounding the interior portion that's not going to make any sense at all on the record, I understand that. Are we talking about the same thing? Is that the	8 9 10 11 12 13 14 15 16 17 18 19 20 21	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more tissue is more nebulous. Q. What is it about the polypropylene structure that causes it to crack in the manner you just described? MR. ANDERSON: Objection to form. Go ahead. A. It's developed brittleness from lack of antioxidants and oxidation and/or stress
9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that and I think of bark on a tree. And there's areas on either side, and then an interior that I would think of as exposed wood on a tree and the rest would be the bark, and I'm trying to use it as kind of a descriptive thing. Is the area surrounding the interior portion that's not going to make any sense at all on the record, I understand that. Are we talking about the same thing? Is that the tissue that's surrounding it?	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more tissue is more nebulous. Q. What is it about the polypropylene structure that causes it to crack in the manner you just described? MR. ANDERSON: Objection to form. Go ahead. A. It's developed brittleness from lack of antioxidants and oxidation and/or stress cracking. The two work together in any given
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. It shows a large this is atypical. It shows a large longitudinal crack in the underlying polypropylene coated by what appears to be tissue. Q. Okay. Which parts I look at that and I think of bark on a tree. And there's areas on either side, and then an interior that I would think of as exposed wood on a tree and the rest would be the bark, and I'm trying to use it as kind of a descriptive thing. Is the area surrounding the interior portion that's not going to make any sense at all on the record, I understand that. Are we talking about the same thing? Is that the tissue that's surrounding it? A. Yes. This would be the polypropylene	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	which is the polypropylene. Does the area outside of that represent tissue or protein? A. I believe so. Q. Okay. A. It doesn't match you can see when polypropylene cracks it gives these sharp sides and jagged edges, whereas this is more tissue is more nebulous. Q. What is it about the polypropylene structure that causes it to crack in the manner you just described? MR. ANDERSON: Objection to form. Go ahead. A. It's developed brittleness from lack of antioxidants and oxidation and/or stress cracking. The two work together in any given sample.
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	Page 150		Page 152
1	point of polypropylene?	1	BY MR. THOMAS:
2	A. Yes.	2	Q. We've got too many papers working
3	Q. Will degradation always alter the	3	here. I apologize.
4	melting point of polypropylene?	4	What is a plasticizer?
5	A. I think it depends on the severity of	5	A. It's generally a low molecular weight
6	the oxidation, the degradation.	6	material that's put inside of a plastic to make
7	Q. How much degradation or oxidation is	7	it more flexible.
8	required to alter the melting point of	8	Q. Do you agree that fat and body tissue
9		9	will be a plasticizer on polypropylene?
10	polypropylene?	10	
11	A. Well, a lot of things affect the		A. Yes, not on, though, in. Only in. It
12	melting point of polypropylene. I'll show you.	11 12	has to get in.
13	This is again from one of the books in my		Q. What does that mean when the fat and
	Turi, on thermal methods. Here's a chart, it	13	body tissue soften the polypropylene?
14	details polypropylene, and I've got melt points	14	A. It just becomes softer, because
15	all the way from 106 to 114 degrees to	15	that's connected with the environmental stress
16	176 degrees, depending on the percent	16	cracking, that's going to get into the polymer
17	crystallinity. Percent crystallinity affects	17	and start swelling the chains.
18	the melt point.	18	Q. Are you familiar with the concept
19	Q. Did you determine the melt point of	19	known as toughness?
20	the mesh that you analyzed in this project?	20	A. Yeah.
21	A. Yes.	21	Q. What is toughness?
22	Q. What did you determine the melt point	22	A. It's resistance to wear.
23	to be, do you remember?	23	Q. Is implanted mesh tougher than
24	A. I'd have to go to the table. There	24	pristine mesh?
25	were different values.	25	A. Not seen the measurements, so I don't
	Page 151		Page 153
1	Q. We'll get to that.	1	know.
2	You use a reference point in your	2	Q. Have you ever analyzed the question of
3	report of 175.	3	whether implanted mesh is tougher than pristine
4	A. That's for a typically crystalline	4	mesh?
5	polypropylene material.	5	A. No.
6	Q. The actual melting point of the	6	Q. What does it mean if implanted mesh is
7	polypropylene you analyzed was lower than that?	7	tougher than pristine mesh?
8	A. It was all lower, which tells me it	8	A. Well, it just means it might be
9	was after the manufacturing process it was	9	tougher in the sense of, I would use the term
10	like 165, I think, roughly, and then it went	10	I'm more like using the term rigid in this case,
11	down from there.	11	that would probably also be considered as part
12	Q. Okay.	12	of this tougher thing. But it also would make
13	A. It varies as a function of molecular	13	it if it's more rigid, it's going to make it
14	weight, it varies as a function of	14	more difficult to move in the body, and the
15	crystallinity.	15	patient will have more difficulty doing exercise
16	Do you want to keep this together? Do	16	and the like with that type of thing.
17	you know where the start is for this? This is	17	Q. If it's tougher
18	•		
19	mine. MD ANDERSON: I think he flipped it	18 19	A. It's tougher
	MR. ANDERSON: I think he flipped it		Q it's less resistant to be brittle
20	over, so we'll just have to figure it out.	20	and break, isn't it?
21 22	THE WITNESS: I don't want to get us	21	A. Well, we also yes, but we also have
ノフ	all mixed up.	22	to consider based on our again, back to our
	MD ANDEDCON TO	2	
23	MR. ANDERSON: There we go.	23	SEM photographs, we also have to consider there
	MR. ANDERSON: There we go. A. We've got it ready if we need it for something else.	23 24 25	SEM photographs, we also have to consider there appears to be two distinctive layers here, there's a surface layer which is cracking and

39 (Pages 150 to 153)

Page 154 Page 156 1 1 there's an underlying layer which is -- has not suggest that the stress cracking phenomenon is 2 2 oriented along the extrusion lines? yet cracked. So the bulk material could be 3 tougher, while the surface layer is more 3 A. No. It doesn't say one way or the 4 4 brittle, at the same time. other. It just says "stress cracking phenomenon 5 5 Q. Okay. in oriented." She's just discussing oriented 6 6 polypropylene. She doesn't say where the cracks A. So I don't know what to make of your 7 term because you're lumping it in the bulk, you 7 are. 8 know, as the entire fiber. And I'm looking at 8 Q. Okay. I understand. Go ahead. 9 9 two fibers, the surface region and then the A. "Has been explained by their 10 underlying region, which is not cracked yet. 10 pronounced skin to core structure. This 11 11 Q. Just to be clear, they are both parts bi-component structure is created by the 12 12 of the same fiber, aren't they? differential cooling rates between the external 13 13 A. They almost look like two separate and internal layers of the monofilaments." When 14 14 it comes out of the dye, the surface cools fibers. 15 15 faster than the inner core. The faster cooling Q. Okay. 16 16 A. And there's publications which outer surface is going to be less crystalline 17 17 indicate the same. than the inner core which stays warm longer, has 18 18 Q. Did you cite those papers in your more time to form crystals as it's cooling. So 19 report? 19 you wind up with two structure types in the 20 20 filament when you're done. A. Yes. 21 21 Q. Which papers are we talking about now? Q. Are you suggesting by this testimony, A. Well, let's see if I can find it for 22 22 Doctor, that it's only the outside of the 2.3 23 you quick. You'll have to bear were me while I polypropylene mesh that's degrading, and the 24 find it. 24 inside is fine? 25 (Witness reviewing document.) 25 MR. ANDERSON: Objection. Page 155 Page 157 1 A. I've got it, I think. This is paper 1 Go ahead. 2 ASIO journal, 1998, Page 199, Mary Celine, 2 A. I'm not suggesting any such thing. 3 "Comparison of in vivo behavior of 3 I'm suggesting that the outer core is 4 polyvinylidene fluoride and polypropylene 4 chemically less crystalline, and hence more 5 5 sutures used in vascular surgery." stress cracking susceptible, than the inner 6 6 She's discussing stress cracking at part. The inner part would still be susceptible 7 7 this point. She says "The reason for stress over time depending on the degree of 8 8 cracking phenomenon in oriented polypropylene implantation in the body to oxidation. 9 monofilaments has been explained by their 9 We have two different things going on 10 pronounced skin/core structure." Those are two 10 at the same time, two layers. There are 11 phases I'm talking about. 11 actually two different kinds of polypropylene, Q. Let me stop you there. 12 12 although that wasn't the intent in the 13 What is oriented polypropylene 13 manufacture I'm sure, but that's what you wind 14 monofilaments? What does that mean? 14 up with. 15 A. It means it's gone through the dye and 15 BY MR. THOMAS: it's oriented longitudinally. We can see those 16 Q. Each of which will require a breakdown 16 17 lines where it's been pulled through the dye, or in the polymer to degrade as described? 17 18 pushed. 18 A. Each of which --19 19 Q. Does that suggest a stress cracking 20 phenomenon occurs through the extrusion lines? 20 Each of which would require a 21 21 A. Well, her purpose here is not to talk breakdown in the polypropylene in order to 22 about that at the moment. It's talking about 22 degrade as described? 23 the bi-component structure. 23 A. Right. And the surface layer being 24 Q. I understand that. 24 less crystalline would also bleed out its But as you read that, does that 25 25 antioxidants faster, it's more amorphous, and so

40 (Pages 154 to 157)

Page 158 Page 160 1 1 it's going to tend to degrade first. And that's temperature was raised in a heat cycle which is 2 2 listed in Table 4, heating conditions. First what we invariably see in the SEMs, we see a 3 3 heat we went from minus 90C to 200C at 10 surface cracking and removal. 4 4 Q. In your analysis of these explanted degrees C per minute. Then we cooled from 200 5 5 meshes, did you ever see a crack all the way back to minus 90 at 10 degrees C per minute. 6 6 through the mesh? And then we reheated a second heat from minus 90 7 7 to 210 degrees C per minute. A. I don't think we did. But I've read 8 about them in the literature, I just never saw 8 The first heating cycle looks at the 9 9 one in the 23 samples we ran, 24 with Batiste. form of the material as received. And then the 10 Q. Do you have any recollection -- strike 10 second heating cycle looks at the innate material itself, heat history of the material 11 11 12 12 erased, so all the samples then go to what's Do you know the greatest crack that 13 called a common heat history. They may not all 13 you observed in any of the meshes that you 14 14 reviewed? have a common heat history in the first heat 15 A. Do I --15 cycle, but, of course, that's the way they 16 16 actually are in the body so that's the most Q. Are you able to point to me the 17 biggest crack on any of the meshes and quantify 17 important one to look at is the Delta H and the 18 18 for me how much that crack is compared to the melting point, the first melting point in the 19 rest of the mesh? I don't want -- if you don't 19 first Delta H. 20 know it, I don't want you to go look. 20 Q. In Table 5, did you provide data for 21 21 A. There is a range, certainly. all of your explant samples? 22 22 A. Let's see. No, there's 15 samples, we Q. Can you quantify in measurement? 23 23 A. Standing here without looking at the had 23. So there were seven that weren't run. 24 pictures, no. 24 Q. Is there a reason why you didn't test 25 Q. Is there anything about the pictures 25 them all? Page 159 Page 161 1 that allows you -- strike that. 1 MR. ANDERSON: Objection. Asked and 2 Did you measure the cracks as a part 2 answered. 3 of your work in this case? 3 Go ahead. 4 A. No. Actually the entire surface was 4 A. I remember we didn't need to run all 5 cracked in many cases, so the entire surface 5 the samples to show the trends, number one. 6 б And number two, some of these cases would simply come off. 7 7 Q. Let's go to Page 60 of your report, there simply wasn't enough material to run. 8 8 BY MR. THOMAS: please. 9 This is the differential scanning 9 Q. Let's go to Page 66, please, the FTIR calorimetry? 10 microscopy. Let's talk about what FTIR 10 11 A. Calorimetry. 11 microscopy is. Tell me what that is, please. Q. Calorimetry. Thank you. We've talked 12 12 A. An FTIR microscope, FTIR instrument, 13 around this a lot today. 13 you radiate the sample with infrared radiation. 14 14 Would you tell me exactly what this is Each type of chemical bond in a molecule will 15 and what it measures? 15 absorb infrared radiation at a different wave A. DSC is a technique that -- where you 16 length. So when you run across a range of wave 16 17 put energy into a pan, against a standard pan in lengths, typically from 4,000 reciprocal 17 18 the other side, and you measure the rate of heat 18 centimeters to 5 or 600 reciprocal centimeters 19 19 absorption or dissipation of a sample as the you get a picture, a literal picture, to a 20 temperature rises or drops. You can both heat 20 chemist anyway, a picture of the bonds in the 21 21 and cool it. molecule that you're looking at. 22 Q. Okay. And tell me how you set out to 22 Q. Now, when you do FTIR analysis, do you 23 measure those things with the DSC methodology? 23 generally have a reference against which to 24 A. Well, a portion of the sample was put 24 measure what you find to match up? 25 25 into the tube, into the sample pan, and then the A. That's always run with references. We

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Page 162 Page 164 1 1 always run -- to make sure the instrument is don't match I know I've got a problem, and I 2 2 stop and fix it, we don't continue. running fine, usually a polystyrene standard is 3 run to make sure all the bands come out where 3 Q. Believe it or not, I think we're 4 4 they should come out. And then CO2 is removed saying the same thing. 5 with a nitrogen purge so you don't have an 5 A. Hopefully so. 6 6 artificial CO2 peak. That's SOP. That's all in Q. I don't use the same words you do. 7 7 A. If you'd like to see the standard, the SOP. 8 Q. Okay. Do you then have a 8 I've got in my book over there. I'll be glad to 9 9 polypropylene reference point against which to show it to you. 10 compare your findings that you shoot here to see 10 Q. Which standard did you use, the 11 11 how they match up? Sadtler? 12 A. Well, we have polystyrene --12 A. The Sadtler. 13 13 polypropylene reference spectra, so -- and we Q. I don't need to see it. 14 run the standard polypropylene mesh, which is, 14 Do you call that a standard? What's 15 in fact, pure polypropylene. So we compare 15 the technical term for that? 16 16 A. No, I call it a check. It is a type 17 Number one, the polystyrene shows the 17 of -- it's part of our SOP. But the standard is instrument is behaving good, up to standard, and 18 18 the polystyrene, it's always run. 19 then the polypropylene is run, it's compared to 19 Q. The Sadtler reference that you talked 20 a known polypropylene spectrum. So if we were 20 about --21 21 to run the mesh and the peaks looked funny we A. Is polypropylene. 22 22 would have caught that. Although that's never Q. And it would be the same sort of 23 happened, because if the polystyrene standard 23 spectrum that appears on Page 67 of your report? 24 comes out right, it's telling you the machine is 24 A. Exactly. 25 working normally. 25 Q. And you would measure the Sadtler Page 165 Page 163 standard for polypropylene against what you find 1 But even if it did for some crazy 1 2 reason, between the time we ran the standard and 2 to see if it matches what you find? 3 the time we ran the polypropylene, we'd 3 A. That's right. In other words, for 4 immediately flag it because we have 4 isotactic polypropylene, which is what Prolene 5 polypropylene standard spectra around. 5 is, we have 841, 973, 997, and 1166 bands, those 6 6 Q. Is the goal of running the FTIR to are the isotactic bands. It's a fingerprint, we 7 7 determine the extent to which what you're call it, of polypropylene, and particularly of 8 8 testing matches up against what you're looking isotactic polypropylene. 9 for; that is, particularly here that you're 9 Q. Do you know of any polypropylene 10 testing the explanted mesh to determine the 10 standards that have a spectra for oxidized 11 extent to which it's consistent with the 11 polypropylene? 12 MR. ANDERSON: Objection. 12 polypropylene that's supposed to be in the mesh? 13 A. Yes. 13 Go ahead. 14 Q. And there are standards against which 14 A. I've seen them. 15 you measure what your findings are? 15 BY MR. THOMAS: A. Correct. 16 Q. Did you attempt to -- where did you 16 17 17 Q. And there will be a standard -- there see them? 18 are a number of different companies that make 18 A. The Sadtler Library. There's a 19 chapter on polypropylenes, and some of them are 19 standard polypropylene spectra against which you 20 could measure your findings? 20 oxidized and some aren't. 21 21 A. Yes. But we don't need that because Q. Okay. Have you read about FTIR 22 we use the spectra, or the known spectra from 22 spectra for oxidized polypropylene? 23 like Sadtler Library of spectra, I will simply 23 A. I've just seen them in the Sadtler 24 look up what I'm getting versus a known 24 Library.

42 (Pages 162 to 165)

Q. Did you consider utilizing spectra for

25

standard, and those two have to match. If they

25

	Page 166		Page 168
1		1	correct?
1 2	oxidized polypropylene when you conducted your FTIR analysis in Lewis and Batiste?	2	
3	A. No. I used more of the literature,	3	MR. ANDERSON: Objection. Form. Go ahead.
	,	4	
4	the Clavés, the Ostergards, and Wood, the		A. I certainly could have used those. I
5	current Wood paper and others. They all run	5	don't see it makes any difference. I'm using
6	infrared of polypropylene.	6	published literature, recent published
7	Q. Why didn't you use the standards which	7	literature here, so I feel very safe. I mean I
8	have oxidized polypropylene against which to	8	could have used the Sadtler Library, sure.
9	measure your findings?	9	BY MR. THOMAS:
10	A. Well, those were those were bulk	10	Q. Well, if the Sadtler Library gave you
11	polypropylenes, this is fiber. So I didn't	11	a different result, you'd be concerned, wouldn't
12	really have any fiber standard spectra to use	12	you?
13	anyway. So I guess I could have used them,	13	A. But it's not going to. I'm confident
14	wouldn't have hurt, wouldn't have made any	14	sitting here it's not going to give me a
15	difference, I don't think.	15	different result. I'll go get the spectra and
16	Q. Why not?	16	show you, glad to.
17	A. Because I already had them from the	17	Q. The range of absorption regions
18	other literature.	18	identified by you as being indicative of
19	Q. But you are measuring something	19	oxidation are 1730 to 1680, is that correct?
20	different with oxidized polypropylene than you	20	A. Right. That would include acids
21	are with regular polypropylene by your own	21	around 1700, ketones around 16 1710, 15, and
22	definition, correct?	22	then aldehydes around 1730, esters around 1740.
23	A. Right. As shown in the literature I	23	Q. Do you have anything did you find
24	already have.	24	anything in your FTIR analysis of evidence of
25	Q. The literature you're talking about is	25	oxidation in the range of 1730 to 1680?
	Page 167		Page 169
1	Clavé?	1	A. It was covered up by the protein that
2	A. Yeah, Clavé and there's others. Wood	2	was in the coating, or part of I guess you
3	is another one, that's 2013.	3	could say coating the fiber pieces.
4	Q. Is that contained in your report?	4	Q. So is the answer no?
5	MR. ANDERSON: Yes.	5	A. The answer is no.
6	A. I think so.	6	Q. Now, when you run these FTIR samples,
7	BY MR. THOMAS:	7	you set the machine, the machine reads it, and
8	Q. May I see that, please?	8	then the machine is what identifies those areas
9	A. Sure. If you want, I'll make you a	9	that are significant and calls them out with
10	copy.	10	numbers, is that right?
11	Q. We'll take care of that later.	11	A. The frequencies of each band, yes, the
12	Just for the record, this is the	12	machine calls out, yes.
13	Journal of Material Science, 2013, 24:1113-1122,	13	Q. The frequencies of each band?
14	A.J. Wood, "Materials Characterization,	14	A. Yes.
15	Historical Analysis of Explanted" I've seen	15	Q. So the numbers that appear, for
16	this before "Polypropylene PTFE and PET	16	example, on Page 69, along with the spectra
17	Hernia Meshes."	17	there, those numbers are placed there by the
			•
18 19	You're referring to the FTIR spectra	18 19	machine based upon your calibration of the
	on Page 1117, is that correct?		machine about what's significant. Is that fair?
20	A. Yes, sir.	20	A. Well, it's simply identifying the
21	Q. And 1118?	21	machine identifies the peaks and labels the
22	A. Yes, that's part of the paper.	22	numbers. I have to interpret what it means.
23	Q. So you relied on this rather than the	23	We also have the computer these
24 25	standards in Sadtler or others that may have	24	days can make estimates and look for matches,
	FTIR spectra for oxidized polypropylene,	25	too.

43 (Pages 166 to 169)

Page 170 Page 172 Q. Okay. On Page 69, you've identified 1 1 liquid or gas, in the case of polypropylene, and 2 2 then as they monitor units, fuse together, the this area at 1757 as being significant, is that 3 3 chains become longer and longer, and then you right? 4 4 A. Right. There's also another region have eventually a polymer -- generally the start 5 5 I'd like to mention, it's a little bit subtle, of what we call a polymers around, it's a bit of 6 6 is that shoulder that's at the base of the 1656 a range, but we generally consider anything 7 7 peak, towards the left side of it, that would be above 2000-ish molecular weight of daltons to be 8 the 1740. The machine didn't pull it out 8 a polymer, albeit a very low molecular weight 9 9 because there's not a baseline, not a valley in polymer. Most commercial polymers are hundreds 10 there for it to see. The machine requires a 10 of thousands to millions. 11 Q. Of what significance to molecular 11 valley to see. But the human eye can see it. 12 12 Q. I see. weight is a breakdown of the polypropylene 13 So that shoulder is something --13 polymer, a change in the polypropylene polymer, 14 14 A. That's the 1740. will it change the molecular weight? 15 Q. -- that the machine didn't find, but 15 MR. ANDERSON: Objection to form. 16 16 you find? Go ahead. 17 17 A. I'm sorry, can I rehear it again? A. Right. The human brain can still be a 18 18 machine occasionally. BY MR. THOMAS: 19 Q. I see. 19 Q. The polypropylene polymer is broken, 20 A. And if I had taken this sample and 20 the chain is broken. 21 21 treated it with sodium hypochlorite, for A. Okay. 22 22 example, then we would have gotten rid of the Q. Will that change the molecular weight? 2.3 23 1656 and the 1541 bands, which are the protein A. It will lower it. 24 bands, because we have destroyed the protein or 24 Q. Page 80. After doing your analysis, 25 the biofilm that was part of the particle or 25 you conclude in your scientific opinion that Page 171 Page 173 1 1 coating the particle, the bulk of which was "The control and explant samples do not show a 2 polypropylene. And then I would have seen only 2 significant difference in molecular weight." 3 polypropylene, what's left. 3 Correct? 4 This figure that's shown here 4 A. That's correct. 5 5 represents -- keep in mind the carbonyl bands Q. Doesn't that mean that there's no б are much stronger than alkyl bands. So the fact б evidence in your molecular weight analysis that 7 7 that they're roughly the same size suggests to polypropylene is degrading? 8 8 me that this material, as I'm looking at it A. It might seem so at first 9 here, is about 75 percent polypropylene and 9 consideration. But remember, the only part of 10 25 percent protein, thereabouts, plus or minus a 10 the polymer that seems to be degrading based on 11 little. And it's oxidized, because I have the 11 the SEM photos is the surface. 1740 and the 1757. And there may be a 1730 and 12 12 So GPC is a bulk technique, I had to 13 a 1715 that I can't see because it's buried 13 dissolve the inside undamaged region as well as 14 14 under the 1656 band, which I could see if in the the broken pieces, but I get one sample. The 15 future we choose to do any more -- like sodium 15 total mixture dissolved. 16 So number one, the effect of the 16 hypochlorite. 17 Q. Page 72. "Molecular weight is often a damaged surface -- my point here is I think if 17 18 crucial factor in determining material 18 we could measure the surface we would see a loss 19 19 properties." in molecular weight, but I had no way to get 20 Did I read that correctly? 20 enough pieces to measure the molecular weight of 21 21 A. Yes, you do. only the surface pieces like I did for the 22 Q. What is molecular weight? 22 infrared spectra. 23 A. It's really a measure of the number of 23 Q. Aren't you speculating what you find? 24 repeat units in a given polymer molecule. 24 A. I am. 25 25 Monomer is the starting material, usually a Q. Until you have the opportunity to test

44 (Pages 170 to 173)

	Page 174		Page 176
1	as you've described, the fact that your	1	he knows it is an inappropriate form of a
2	molecular weight testing does not show a	2	question.
3	significant difference in molecular weight	3	MR. THOMAS: Okay.
4	suggests that there's no degradation of the	4	MR. ANDERSON: If you think somebody
5	polypropylene. That's the best scientific	5	from Jordi Labs testified there, then I think
6	conclusion you can reach in this data, isn't	6	that would differ from reality.
7	that true?	7	MR. THOMAS: I wasn't talking about
8	A. It's one of the conclusions, yes.	8	Jordi Labs testifying.
9	Q. It's	9	MR. ANDERSON: That's what it says.
10	A. It's not the only one.	10	MR. THOMAS: Got you.
11	Q. It's fair to say okay.	11	BY MR. THOMAS:
12	Now, has Jordi Labs analyzed	12	Q. Dr. Jordi, are you aware that Jordi
13	polypropylene mesh for other manufacturers?	13	Labs conducted analysis on Bard mesh for use by
14	A. I don't run the day-to-day operations	14	the Plaintiffs in the Bard mesh litigation?
15	anymore, so I would have no way to answer that	15	MR. ANDERSON: Objection. Asked and
16	question. I don't know what has come in.	16	answered.
17	Q. Do you know?	17	A. I am not.
18	A. I do not know.	18	BY MR. THOMAS:
19	Q. Do you know whether Jordi Labs	19	Q. If Jordi Labs had analyzed
20	analyzed Bard mesh that was at issue in the West	20	polypropylene mesh used for pelvic floor
21	Virginia litigation?	21	implants and found a loss of molecular weight in
22	A. I don't know.	22	that mesh, would that be relevant to your
23	Q. Do you know whether Bard mesh has	23	opinions in this case?
24 25	antioxidants in it?	24 25	MR. ANDERSON: Objection.
∠5	A. I haven't been requested to analyze,	∠5	Go ahead.
	D 17F		
	Page 175		Page 177
1	so I don't know.	1	A. I don't have enough information from
2	so I don't know. Q. Do you know whether Bard mesh loses	2	A. I don't have enough information from just that question to answer it. I'd have to
2 3	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing?	2	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels
2 3 4	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no.	2 3 4	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on.
2 3 4 5	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no. Q. You've not seen the work that Jordi	2 3 4 5	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on. BY MR. THOMAS:
2 3 4 5 6	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no. Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation	2 3 4 5 6	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on. BY MR. THOMAS: Q. Okay. Are you suggesting by your
2 3 4 5 6 7	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no. Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation where they where Jordi Labs, your company,	2 3 4 5 6 7	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on. BY MR. THOMAS: Q. Okay. Are you suggesting by your testimony in this case that the polypropylene in
2 3 4 5 6 7 8	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no. Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation where they where Jordi Labs, your company, testified the Bard mesh without antioxidants had	2 3 4 5 6 7 8	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on. BY MR. THOMAS: Q. Okay. Are you suggesting by your testimony in this case that the polypropylene in the Ethicon mesh depolymerizes?
2 3 4 5 6 7 8 9	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no. Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation where they where Jordi Labs, your company, testified the Bard mesh without antioxidants had showed a loss in molecular weight, is that true?	2 3 4 5 6 7 8 9	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on. BY MR. THOMAS: Q. Okay. Are you suggesting by your testimony in this case that the polypropylene in the Ethicon mesh depolymerizes? A. In the Ethicon mesh?
2 3 4 5 6 7 8 9	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no. Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation where they where Jordi Labs, your company, testified the Bard mesh without antioxidants had showed a loss in molecular weight, is that true? MR. ANDERSON: Objection to form.	2 3 4 5 6 7 8 9	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on. BY MR. THOMAS: Q. Okay. Are you suggesting by your testimony in this case that the polypropylene in the Ethicon mesh depolymerizes? A. In the Ethicon mesh? Q. Yes.
2 3 4 5 6 7 8 9 10	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no. Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation where they where Jordi Labs, your company, testified the Bard mesh without antioxidants had showed a loss in molecular weight, is that true? MR. ANDERSON: Objection to form. Assumes facts not in evidence.	2 3 4 5 6 7 8 9 10	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on. BY MR. THOMAS: Q. Okay. Are you suggesting by your testimony in this case that the polypropylene in the Ethicon mesh depolymerizes? A. In the Ethicon mesh? Q. Yes. A. It obviously hasn't depolymerized if
2 3 4 5 6 7 8 9 10 11 12	so I don't know. Q. Do you know whether Bard mesh loses its molecular weight upon testing? A. I haven't seen the Bard mesh, so no. Q. You've not seen the work that Jordi Labs did for Plaintiffs in the Bard litigation where they where Jordi Labs, your company, testified the Bard mesh without antioxidants had showed a loss in molecular weight, is that true? MR. ANDERSON: Objection to form. Assumes facts not in evidence. A. Say again?	2 3 4 5 6 7 8 9 10 11 12	A. I don't have enough information from just that question to answer it. I'd have to know what the antioxidants were, what the levels were, and so on. BY MR. THOMAS: Q. Okay. Are you suggesting by your testimony in this case that the polypropylene in the Ethicon mesh depolymerizes? A. In the Ethicon mesh? Q. Yes. A. It obviously hasn't depolymerized if the molecular weight is the same.
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45 (Pages 174 to 177)

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10 far. 10 Invoice number 7882 dated	Ψ .ε,ε /ε.
11 BY MR. THOMAS: 11 September 11, 2013, in the amount of \$1	13.980.42.
Q. It's the same across every sample that 12 Invoice number 7884 dated	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
13 you tested? 13 September 11, 2013, in the amount of \$6	5.122.94.
14 A. Yes, in this case, in this particular 14 Invoice number 7984 dated Octob	
15 set of samples it was. 15 the 10th, 2013, in the amount of \$28,130	
16 Q. And it's the same with the Burkley 16 And invoice number 8035 dated	
17 seven year dog study? 17 October 28, 2013, in the amount of \$28,	876.05.
18 A. Yes. That's what Dan Burkley said, 18 To the best of your knowledge, is	
19 yes. 19 the total of the billing that you've made i	
Q. Every time you've tested the molecular 20 connection with your work in this case?	
21 weight of Ethicon's mesh or gone back and 21 A. To this point, yes. There's no oth	
retested the molecular weight of Ethicon's mesh, 22 bills. I'm sure there will be another one	
23 the molecular weight hasn't changed in a 23 coming.	
24 significant manner? 24 Q. Obviously in your work in this ca	ase
A. No, we don't see it it's true, we 25 you've analyzed a number of different ex	
Page 179	Page 181
1 do not see a 1 samples?	
2 Q. As a matter of fact, there's never 2 A. Correct. 23; 24 with Batiste.	
3 been a time where you've analyzed Ethicon mesh 3 Q. Are you able to tell from these	
4 used in these TVT products that shows a change 4 invoices the extent to which your work h	has
5 in molecular weight? 5 focused on the Carolyn Lewis case, or is	
6 MR. ANDERSON: Objection. Asked and 6 this for the Carolyn Lewis case?	, u ii 01
7 answered. 7 MR. ANDERSON: I'm not sure I	-
8 But answer it again. 8 understand the question. It could be more	
9 A. That's true. That's correct. 9 in nature, so due to that I will object.	10 10gui
10 BY MR. THOMAS: 10 BY MR. THOMAS:	
Q. Dr. Jordi, during lunch I was provided 11 Q. Are you able to look at these bills	S
with invoices from your office to Mr. Anderson. 12 and tell me the extent to which you work	
13 I'll read these into the record, if you don't 13 the Lewis specific matter, for example, p	
14 mind. 14 the time when you received the Lewis ex	
15 A. That's fine. 15 separate and apart from the others that y	
Q. Do you want me to do it so you can see 16 analyzed, and determine the cost that yo	
17 so I do it right? 17 incurred in analyzing the Lewis explant?	
18 MR. ANDERSON: What are you trying to 18 don't know if you can or not.	
19 point out, just amounts? 19 MR. ANDERSON: I'm just going	g to
MR. THOMAS: Just the dates and 20 object to the form, because I think you'v	
21 amounts. 21 two different things. One is you're asking.	
22 BY MR. THOMAS: 22 much of the work was case specific, and	
Q. On August the 12th, 2013, invoice 23 general expert as well as looking at the	
24 7783, for \$11,250. 24 specific explant of Ms. Lewis.	
August the 28th, 2013, invoice number 25 So if you want us to look at the bil	11

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	Page 182		Page 184
1	and see just how much the cost was of the	1	there next to it. That would be the 1740.
2	testing and the analysis for just Lewis, we will	2	Q. Let's go one at a time.
3	try to do that. But to mix that up and to say	3	The first one you said a minute ago,
4	how much of the cost related to just Ms. Lewis,	4	the carbonyl band where?
5	as you know at the trial he's going to be	5	A. Around 1759. Some of these, there's
6	talking about all of these things.	6	no valley there, so the machine didn't actually
7	So I just want to make sure we're on	7	label it. If you go to the next page, 72, it's
8	the same page and that's clear, because your	8	very similar, you'll see there it does have a
9	question was not.	9	slight valley, so the machine calls it 1761. I
10	MR. THOMAS: Thank you. I thought my	10	think we showed another one that was 1757. It's
11	question was clear, but that's good.	11	in that region, all of them.
12	BY MR. THOMAS:	12	Q. Is there any discussion in your report
13	Q. Can you tell me the extent to which	13	anywhere, specifically text, about your findings
14	MR. ANDERSON: We agree to disagree.	14	with respect to Carolyn Lewis?
15	MR. THOMAS: I understand. I'm going	15	MR. ANDERSON: You mean in one place?
16	to try to ask the question better now.	16	MR. THOMAS: Anywhere.
17	BY MR. THOMAS:	17	BY MR. THOMAS:
18	Q. Can you look at these invoices,	18	Q. About "this is what I find wrong with
19	Dr. Jordi, and tell me about the Lewis specific	19	Carolyn Lewis based on this analysis."
20	analysis that you did, and the cost of that?	20	MR. ANDERSON: He's pointing to one
21	MR. ANDERSON: We'd have to get more	21	right now. I don't understand.
22	material to be able to do that. We tried to	22	MR. THOMAS: I understand that, Ben.
23	bring everything in here to be able to do that,	23	BY MR. THOMAS:
24	we've got lab notebooks to when those days would	24	Q. Do you explain anywhere
25	be as opposed to the billing. The problem is	25	A. I explain the principles in the
	Page 183		Page 185
1	the billing is through a time period, so we'd	1	conclusions. It applies to all the explanted
2	have to try to look and match up the time period	2	samples, including Carolyn Lewis, but not
3	in the lab notebook to when it was received with	3	specifically Carolyn Lewis.
4	the time period on the invoice. We're happy to	4	Q. Okay. So there are no specific
5	take the time to try to do that.	5	opinions in your report that relate to Carolyn
6	MR. THOMAS: I'd like to use my time	6	Lewis, is that fair?
7	better than that.	7	MR. ANDERSON: Objection to form.
8	I'm going to mark these invoices	8	THE WITNESS: Answer?
9	collectively as Exhibit Number 5.	9	MR. ANDERSON: You can answer.
10	MR. ANDERSON: Sure.	10	A. Not that I no.
11	(Whereupon, Jordi Exhibit Number 5,	11	BY MR. THOMAS:
12	Group of invoices from Jordi Labs, was	12	Q. Okay. So it's correct that there are
13	marked for identification.)	13	no specific opinions to Carolyn Lewis in your
14	BY MR. THOMAS:	14	report, correct?
15	Q. Dr. Jordi, what are your opinions with	15	MR. ANDERSON: Objection.
16	respect to the mesh explant of Carolyn Lewis?	16	A. Well, there are.
17	If you're going to your report, tell me where	17	MR. ANDERSON: That's unfair.
18	you're going, please.	18	Go ahead.
19	A. As soon as I get there and find	19	A. There are, because it's the photos.
20	something, I will.	20	You want it text, but it's in the presence of
21	Page 71. So that's the infrared, one	21	the printed results.
22	of the shards from Carolyn Lewis. Sample 13674	22	BY MR. THOMAS:
23	showing carbonyl band highlighted there in	23	Q. Okay. But you don't describe anywhere
24	yellow.	24	in your report what, for example, Figure 81
25	There's a second shoulder you can see	25	means to you in your interpretation, correct?

47 (Pages 182 to 185)

	Page 186		Page 188
1	A. I describe in general what all these	1	Carolyn Lewis mesh?
2	figures like this mean. So if it's a carbonyl	2	A. The cracking.
3	for Carolyn Lewis, or it's a carbonyl for any of	3	Q. That's the perpendicular cracking?
4	the other explants, it's the same meaning.	4	A. The perpendicular cracking. And then
5	Q. I see.	5	we also have a parallel flaking which you can
6	So when you point out this shoulder on	6	see at the top, at the bend where it goes
7	Page 71 in Figure 81 that's not marked in any	7	particles getting ready to come off. And
8	way, that's something that you see on the	8	there's also tissue on top of that.
9	drawing, that you're the one who identifies that	9	Q. Now, is this the portion of the mesh
10	and can only testify to that because you can see	10	that you tested with FTIR analysis?
11		11	A. It is not.
12	it; fair?	12	Q. Okay.
13	MR. ANDERSON: Objection to the form	13	= •
14	of the question.	14	A. Remember, we didn't want to cause any
15	Go ahead.		stress or strain on these meshes, so we simply
	A. Well, due to my experience reading	15	sent it imbedded in tissue. For the IR you must
16	FTIRs, yes, I can see it. Anyone else with	16	remove the tissue in order to get the spectrum.
17	equivalent experience would see it, too.	17	Q. Okay. What else do you have for
18	BY MR. THOMAS:	18	Carolyn Lewis?
19	Q. Well, I'm lawyer and a history major,	19	A. Okay. SEM-EDX, let's find that chart.
20	would you expect me to be able to figure that	20	58, Page 58.
21	out?	21	Q. On Figure 71, you have is that a
22	MR. ANDERSON: No comment.	22	different image still than the one that was on
23	A. No comment.	23	48?
24	BY MR. THOMAS:	24	A. Yeah. It is, yes.
25	Q. Okay. Certainly not apparent to	25	Q. All right. And the J8041 means what?
	Page 187		Page 189
1	somebody without your training as to what is	1	A. That's the job number.
2	somebody without your training as to what is shown in Figure 81. Would you agree with that?	2	A. That's the job number.Q. Okay.
	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could		A. That's the job number.
2	somebody without your training as to what is shown in Figure 81. Would you agree with that?	2	A. That's the job number.Q. Okay.
2 3	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could	2	 A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were
2 3 4	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it.	2 3 4	A. That's the job number.Q. Okay.A. 13674 is sample number.Q. And what does this show you?
2 3 4 5	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your	2 3 4 5	 A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for
2 3 4 5 6	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis?	2 3 4 5 6	 A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to
2 3 4 5 6 7	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and	2 3 4 5 6 7	 A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for
2 3 4 5 6 7 8	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We	2 3 4 5 6 7 8	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below
2 3 4 5 6 7 8 9	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through.	2 3 4 5 6 7 8 9	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right
2 3 4 5 6 7 8 9	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM.	2 3 4 5 6 7 8 9	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box.
2 3 4 5 6 7 8 9 10	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and	2 3 4 5 6 7 8 9 10	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that?
2 3 4 5 6 7 8 9 10 11 12	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there.	2 3 4 5 6 7 8 9 10 11 12	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the
2 3 4 5 6 7 8 9 10 11 12 13 14	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent?	2 3 4 5 6 7 8 9 10 11 12 13	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen,
2 3 4 5 6 7 8 9 10 11 12 13	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue.	2 3 4 5 6 7 8 9 10 11 12 13 14	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a
2 3 4 5 6 7 8 9 10 11 12 13 14 15	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay. A. And then the picture 60 is of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay. A. And then the picture 60 is of the actual region that they were we were able to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample pan that doesn't mean anything, phosphorus and
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay. A. And then the picture 60 is of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample pan that doesn't mean anything, phosphorus and sulfur are at fairly large peaks on this region
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay. A. And then the picture 60 is of the actual region that they were we were able to get I was able to get a photo micrograph of the fiber.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample pan that doesn't mean anything, phosphorus and sulfur are at fairly large peaks on this region of the spectrum.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay. A. And then the picture 60 is of the actual region that they were we were able to get I was able to get a photo micrograph of the fiber. Q. Do you know which part of Figure 59 is	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample pan that doesn't mean anything, phosphorus and sulfur are at fairly large peaks on this region of the spectrum. Now, that's the cracked region, and
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay. A. And then the picture 60 is of the actual region that they were we were able to get I was able to get a photo micrograph of the fiber. Q. Do you know which part of Figure 59 is depicted in Figure 60?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample pan that doesn't mean anything, phosphorus and sulfur are at fairly large peaks on this region of the spectrum. Now, that's the cracked region, and has a large amount of oxygen. But we also
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay. A. And then the picture 60 is of the actual region that they were we were able to get I was able to get a photo micrograph of the fiber. Q. Do you know which part of Figure 59 is depicted in Figure 60? A. No, not specifically.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample pan that doesn't mean anything, phosphorus and sulfur are at fairly large peaks on this region of the spectrum. Now, that's the cracked region, and has a large amount of oxygen. But we also thought that the cracked region also, well,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	somebody without your training as to what is shown in Figure 81. Would you agree with that? A. Without training, none of us could read an infrared. We all have to learn it. Q. What else do you have specific in your report to Carolyn Lewis? A. Well, see if I can find the SEM and the SEM-EDX. See if we can find the SEM. We can just work our way through. Page 48 is the SEM. Q. Okay. Let's stop there. On Page 48 you have Figure 59, and that's what does that represent? A. That's the tissue with the mesh imbedded in the tissue. Q. Okay. A. And then the picture 60 is of the actual region that they were we were able to get I was able to get a photo micrograph of the fiber. Q. Do you know which part of Figure 59 is depicted in Figure 60?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's the job number. Q. Okay. A. 13674 is sample number. Q. And what does this show you? A. The boxes are the regions that were tested. So like Spectrum 3, if you go down to the you can see the pink box at the top for Spectrum 3, right? Now, if you go down below you'll see in yellow Spectrum 3, upper right corner of the bottom box. Do you see that? Q. Yes. A. That's just telling you that the yellow spectrum is this region of the specimen, region 3. And so you'll see you have a peak, a fairly large peak for oxygen, a huge peak for carbon, sodium, aluminum which is just a sample pan that doesn't mean anything, phosphorus and sulfur are at fairly large peaks on this region of the spectrum. Now, that's the cracked region, and has a large amount of oxygen. But we also

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Page 190 Page 192 1 1 sulfur levels. So that could mean phosphate and or sulphur. That is the increased oxygen that I 2 2 sulfate which also contain oxygen, so the call oxidation. 3 3 increased oxygen in that region could have been Q. Okay. Again, so Spectrum 3 is meant 4 4 from buffers as well as just literally the to be testing the oxidized polypropylene, 5 oxidation type oxygen. 5 correct? 6 6 So you want to go to region of the A. Right. That's why we ran it there 7 7 polymer that wasn't cracked, there's Spectrum 4. first. 8 And that is the red one. It's hard to read in 8 Q. Spectrum 4 is designed to testify --9 9 the picture but it's -- the red is Spectrum 4. excuse me. 10 Now you see -- you still see an oxygen peak, 10 Spectrum 4 is designed to test what 11 although it's lower in the Spectrum 3, but now 11 you believe to be clean polypropylene? 12 the sodium is almost totally gone, and the 12 A. Let's phrase it this way. 13 phosphorus and sulfur are basically gone 13 Not yet degraded. Not yet cracked. 14 14 But I didn't know whether -- if it has increased completely. 15 So what this is telling me is even in 15 oxygen in it, that means it's on its way to 16 16 the non-cracked region, I have a higher than cracking. 17 baseline level of oxygen. If you want to see 17 What I believe is happening is layer 18 that in another --18 after layer after layer of this stuff is going 19 Q. Before you do that, may I ask you 19 to crack depending on the implantation time. 20 another question? 20 The first layer is going to go quickest because 21 21 A. Sure. it's -- remember the outer layer is less 22 22 Q. I don't want to interrupt you. crystalline, remember the paper I showed you 23 2.3 earlier, and so it's going to go first. And A. Go ahead. 24 Q. Spectrum 4 shown in red, are you 24 when it peels off, as some of it's flaked off 25 suggesting that what you're testing in Spectrum 25 here, then we expose more underlying fresh Page 191 Page 193 1 4 is pure polypropylene? 1 surface, which then begins to itself oxidize as 2 A. Yes. 2 reflected in the increased oxygen even in that Q. Okay. Without any kind of 3 3 region, which is the red peak for oxygen. 4 contamination at all? 4 Q. What is Spectrum 2? 5 5 A. We got away from the -- you can see A. We just didn't show it. 6 б Q. Did you run the data? this white material here, which would be the 7 7 polypropylene -- which would be tissue. A. Yeah, I could show it. I could get 8 8 Q. Okay. it. I don't have it with me. 9 A. Which you might call biofilm. We'll 9 Q. It's not in your report? A. It might be. Do you want to see if I 10 have to agree to disagree or agree to agree and 10 11 use both terms interchangeably. So I wanted to 11 can find it? get away from that as much as possible, so we 12 12 Q. Just curious, yes. 13 ran a cleaner spectra -- cleaner region that 13 A. Glad to try. If we don't have it, we 14 didn't have cracks in it. 14 certainly can get it. 15 Now, when I look at this, I see this 15 Q. It won't be in the controls, will it? 16 cracked material in many places is flaked off. 16 A. That doesn't mean anything, because 17 You can see the edge over here on the right 17 I've got -- this is LCMS. It's not in exact. 18 where the piece has actually come off and it's 18 Here we go. Now I've got -gone. You can see the edge where it was. And 19 (Witness reviewing document.) 19 20 the same is true on the other side. But on this 20 MR. ANDERSON: We'll go off the record 21 21 left side of it, it's clean. And then left of while we're looking. Is that okay with you, 22 it up there's really nothing but straight --22 Dave? 23 pretty much straight clean-ish polypropylene. 23 MR. THOMAS: Yes. 24 So we ran a spectrum of that, and we still saw 24 (Off the record discussion.) 25 25 increased oxygen. But no increased phosphorus (Whereupon, a recess was taken from

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-	Page 194		Page 196
1	2:47 p.m. to 2:53 p.m.)	1	bottom of Table 5 for sample ID number 13674.
2	A. He's got a box on the Spectrum 2 so	2	A. Correct. So and now we compare
3	I'm almost sure it's run, so we'll just have	3	that with the first heat effusion for the
4	if you want that spectrum, I don't see it in	4	control samples, you can see that they range
5	the number one, the reason it's not there is	5	from 93, 79, 82, 86. Table 7 probably says it
6	because it's also on a cracked region just like	6	best. We do for the samples, we had a couple
7	Spectrum 3 is, so what it's going to look like	7	samples that didn't show any cracking on the
8	is the higher the one in yellow, it's just a	8	average of FLP for those samples was 86.6
9	duplicate of the one in yellow.	9	kilograms per gram or joules per gram, sorry.
10	BŶ MR. THOMAS:	10	And moderate cracking at 81.2, and highly
11	Q. I understand, Doctor. So for reasons	11	cracked at 75.1. And here we're at 69.77, so
12	I'm sure you understand, I'd like to have a copy	12	we're in that highly cracked region in terms of
13	of it.	13	this measurement.
14	MR. ANDERSON: Yes.	14	Q. Does this DSC testing that you did,
15	BY MR. THOMAS:	15	which you used to suggest that this is evidence
16	Q. Just so the record is clear, you've	16	of oxidation, does this also capture the extent
17	searched your files that you brought with you	17	to which there are any impurities in the sample?
18	A. I can't find it.	18	A. I would say, number one, it doesn't
19	Q and you're unable to find the	19	necessarily correlate with oxidation, although
20	Spectrum 2 data that appears on Page 58 of	20	it could. But it also correlates with possible
21	Exhibit 1?	21	stress cracking.
22	MR. ANDERSON: Is that correct?	22	Q. Okay.
23	A. That's correct.	23	A. Because there's less crystallinity.
24	BY MR. THOMAS:	24	Q. Let me ask this question again.
25	Q. Thank you.	25	You are using this DSC data to suggest
	Page 195		Page 197
1	Okay. We were talking about evidence	1	that the lower melting point reflects either
2	that you had specific to Carolyn Lewis.	2	oxidation or stress environmental stress
3	A. So the net result here is that we have	3	cracking. Does it also capture any impurities
4	oxygen in the clean looking, undegraded looking	4	1 1 1 1 1 0
	. 64 64 4 4 1 4 1 1		that may have been in the sample?
5	region of the fiber that's under the cracked	5	A. If there were impurities in the
6	region suggesting that it's beginning to oxidize	5 6	A. If there were impurities in the sample, they would also tend to lower the melt
6 7	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's	5 6 7	A. If there were impurities in the sample, they would also tend to lower the melt point.
6 7 8	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked.	5 6 7 8	A. If there were impurities in the sample, they would also tend to lower the melt point.Q. Okay. Are you able to tell from this
6 7 8 9	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay.	5 6 7 8 9	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values
6 7 8 9 10	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC.	5 6 7 8 9	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress
6 7 8 9 10 11	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is	5 6 7 8 9 10 11	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities?
6 7 8 9 10 11	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion.	5 6 7 8 9 10 11	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No.
6 7 8 9 10 11 12 13	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram.	5 6 7 8 9 10 11 12	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about
6 7 8 9 10 11 12 13 14	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that?	5 6 7 8 9 10 11 12 13 14	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that
6 7 8 9 10 11 12 13 14	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No.	5 6 7 8 9 10 11 12 13 14 15	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress
6 7 8 9 10 11 12 13 14 15 16	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table,	5 6 7 8 9 10 11 12 13 14 15	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on?
6 7 8 9 10 11 12 13 14 15 16 17	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table, under heat effusion for TM.	5 6 7 8 9 10 11 12 13 14 15 16 17	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on? A. The value of her heat effusion is very
6 7 8 9 10 11 12 13 14 15 16 17	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table, under heat effusion for TM. Q. What page are you on?	5 6 7 8 9 10 11 12 13 14 15 16 17	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on? A. The value of her heat effusion is very low, 69.77.
6 7 8 9 10 11 12 13 14 15 16 17 18	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table, under heat effusion for TM. Q. What page are you on? A. Page 63.	5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on? A. The value of her heat effusion is very low, 69.77. Q. And you're unable to tell me the
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table, under heat effusion for TM. Q. What page are you on? A. Page 63. Q. I'm sorry, I was on 62.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on? A. The value of her heat effusion is very low, 69.77. Q. And you're unable to tell me the extent to which that is oxidation and
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table, under heat effusion for TM. Q. What page are you on? A. Page 63. Q. I'm sorry, I was on 62. A. Go up. First table, Table 5.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on? A. The value of her heat effusion is very low, 69.77. Q. And you're unable to tell me the extent to which that is oxidation and environmental stress cracking as opposed to
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table, under heat effusion for TM. Q. What page are you on? A. Page 63. Q. I'm sorry, I was on 62. A. Go up. First table, Table 5. Q. Okay.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on? A. The value of her heat effusion is very low, 69.77. Q. And you're unable to tell me the extent to which that is oxidation and environmental stress cracking as opposed to impurities?
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table, under heat effusion for TM. Q. What page are you on? A. Page 63. Q. I'm sorry, I was on 62. A. Go up. First table, Table 5. Q. Okay. A. Last line of that table, and then the	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on? A. The value of her heat effusion is very low, 69.77. Q. And you're unable to tell me the extent to which that is oxidation and environmental stress cracking as opposed to impurities? A. Well, I don't think we're not
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	region suggesting that it's beginning to oxidize as well, but it's not enough yet that it's actually cracked. Q. Okay. A. So we'll go to DSC. Okay. So the first thing you do is look at Table 5, then look at the heat effusion. First heat is 69.77 joules per gram. Do you see that? Q. No. A. Table 5, last entry in the table, under heat effusion for TM. Q. What page are you on? A. Page 63. Q. I'm sorry, I was on 62. A. Go up. First table, Table 5. Q. Okay.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. If there were impurities in the sample, they would also tend to lower the melt point. Q. Okay. Are you able to tell from this DSC testing the extent to which the values reflect oxidation, environmental stress cracking, as opposed to impurities? A. No. Q. All right. Now, what is it about Ms. Lewis's values that suggest to you that there's oxidation or environmental stress cracking going on? A. The value of her heat effusion is very low, 69.77. Q. And you're unable to tell me the extent to which that is oxidation and environmental stress cracking as opposed to impurities?

50 (Pages 194 to 197)

Page 198 Page 200 1 1 different, totally different mechanisms for Table 18, Page 92. The control samples showed 2 2 degradation of the polymer. Both are anywhere from 71 million counts to 92 million 3 3 degradation, but one is physical mechanical counts. In this case, we also ran formalin 4 4 degradation where the chains are forced to part treated control samples which showed levels that 5 and they crack, and the other is actual literal 5 were right in the middle of the controls, some 6 6 oxidation. They're different. were higher, some were lower, fit the normal 7 7 Q. Let me ask the question different, range for controls, indicating formalin didn't 8 because that wasn't what I was trying to get at. 8 extract the lauryl thiodipropionate. 9 9 It's fair to say you don't know the So the level for Ms. Lewis was 611,000 10 extent to which impurities in the test sample 10 compared to 80 million, so it's about in the 2 11 11 may have contributed to the low heat effusion percent range left for the lauryl 12 12 values for Carolyn Lewis as reflected on Table 5 thiodipropionate antioxidant compared to the 13 controls, and the formalin controls. 13 on Page 63, correct? 14 A. Correct. 14 Q. Okay. Let's talk about Page 92 for a 15 Q. Thank you. 15 minute. 16 16 What else do you have for Ms. Lewis? Here you have control samples again? 17 17 A. FTIR. Page 71, Figure 81, Figure 82. A. Right. 18 18 We have, again, the carbonyl that are on 1760 Q. Why do you do a duplicate control like 19 and another one around -- the shoulder is about 19 you do on 3422128? Do you have do that as a 20 1740, that's under that large 1653 amide 1 band. 20 test? 21 21 Q. Okay. Let me stop you here for a A. Yes. A test to see how reproducible 22 22 second. the material itself might be. 2.3 23 Q. Okay. Or how reliable your test might Figure 81 says "Microscopy images 24 24 showing particles recovered from explant sample be? 25 13674 (particle 1)." 25 A. Well, I suppose that's another way to Page 199 Page 201 1 How many particles did you remove from 1 look at it. 2 Ms. Lewis's explant? 2 Q. And --3 A. Didn't count them. Lots. The surface 3 A. But we ran standards, and we get the 4 sluffs off. 4 same -- we make the injection standards twice, 5 Q. Did you analyze any others? This is 5 we get the same area, so that's not --6 б noted as particle 1. That suggests to me that Q. My point being is that for control 7 7 there are others that are identified? sample 3422128, you've got 71,633,460, and then 8 8 A. Right. you test exactly the same mesh in a different 9 No. 9 place in the mesh in the duplicate control and Q. No what? No, you don't know, or no --10 you get 96 thousand 522 --10 A. No, it wasn't the only one analyzed. 11 A. 96 million, yes. 11 12 12 Q. Do you still have the others? Q. Thank you. -- 96,522,909, which is about 13 A. I don't know. I have to check. 13 14 14 Q. Was it your practice to keep those 40 percent more than your other control. 15 things following an experiment like this? 15 A. We could be extracting regions of the A. If there was anything to keep, yes. 16 mesh that have flaked off the polypropylene that 16 17 It was very, very minimal samples here. we see flaked off in the IR, and what we're 17 18 Q. Are you able to tell me how many 18 extracting here is a residual, call it clean particles there are --19 19 mesh. 20 A. No. 20 Q. You don't know why there's a 21 21 Q. -- from Ms. Lewis's sample? 40 percent difference in the test of the same 22 A. I'm not. 22 23 Q. Anything else from Ms. Lewis? 23 A. No. But I would suspect there's a 24 (Witness reviewing document.) 24 change in the mesh, either because the mesh A. The amount of lauryl thiodipropionate, 25 25 itself isn't uniform, or because maybe it's

51 (Pages 198 to 201)

	Page 202		Page 204
1	because the polypropylene, the cracked	1	A. True.
2	polypropylene is gone in that region at that	2	Q. Okay. Anything else on Carolyn Lewis?
3	point, and we are just extracting the enriched	3	A. I think we've pretty well covered it.
4	area only.	4	I think I can show you well, one
5	·	5	other thing that might be of interest if we look
6	Q. Okay.	6	
7	A. I think that would easily account for	7	at Table go back and look at that table for a
8	that difference.		minute longer, and just pick arbitrarily 13411,
	Q. But do you have a scientific	8	it has 12 million area counts for
9	explanation for the reasons why the same piece	9	Q. What page are you on, please?
10	of mesh tests differently by some 28 million	10	A. Same page, 92.
11	DAs?	11	Q. I put mine away. I have to figure out
12	MR. ANDERSON: Other than what he just	12	the pages.
13	testified to?	13	A. Okay.
14	BY MR. THOMAS:	14	Q. Okay.
15	Q. Scientific explanations or reasonable	15	A. So now that's a relatively higher
16	scientific certainty, do you have the answer to	16	level than any of the others, isn't it, for the
17	the question?	17	antioxidants, so what would I expect to see? I
18	A. I think I just gave it, my estimate of	18	would expect to see less cracking in that sample
19	the	19	if I went back and my theory is right, my
20	Q. Is that your opinion to a reasonable	20	scientific opinion is right. So let's go look
21	degree of scientific certainty what happened, or	21	at the SEM photograph for 13411, which will be
22	are you just positing it as something you need	22	the actual degree of cracking, and just see if
23	to test?	23	it correlates or not.
24	A. I think it's reasonable, yes.	24	Q. What page is it?
25	Q. Reasonable degree of scientific	25	A. I'm looking. I'm getting close. It's
	Page 203		Page 205
1	certainty, is that the answer to the problem?	1	37.
2	A. Yes. I think it's reasonable degree	2	Q. Page 37?
3	of scientific certainty with this one. Because	3	A. Right. I would expect to see a low
4	we didn't extract the formalin didn't do	4	degree of cracking due to the high level of
5	anything to the polymer in this case, showing me	5	antioxidant still there, and there it is. It's
6	it's not coming out of the polymer at least	6	minimally cracked.
7	the formalin isn't able to extract it out of the	7	Q. That's the one photo you have of all
8	polymer because you're right in the heart of the	8	this mesh?
9		9	MR. ANDERSON: What?
10	average. Q. Well, if you look at 3405405, the	10	BY MR. THOMAS:
11	control is 79, and the formalin control is 10	11	Q. Strike that, I'm sorry.
	· ·		•
12	million less, isn't it? And the same with	12	So you point to Figure 38 on Page 37
13	3422128, you've got 96,522,000, and the control	13	as suggesting that suggesting what?
14	was 17 million less, isn't it?	14	A. Minimal, this is what we would call
15	A. Do you have any idea, though, what	15	minimal cracking.
16	how the ratios are working out here? You're	16	Q. Okay.
17	talking about a 20 percent change down here, and	17	A. And it correlates with a high level of
18	I'm talking about a 100-fold change up above.	18	antioxidant. So it's being protected, doesn't
19	Q. I know that.	19	react, doesn't crack. Or it doesn't crack as
20	A. It's irrelevant.	20	much, it obviously is still cracking some, but
21	Q. Except we don't know how long these	21	it's minimal.
22	mesh explants were in formalin, do we?	22	Q. Anything else for Carolyn Lewis?
23	A. We put these other ones in formalin	23	A. No.
24	and nothing happened.	24	Q. Let's go now to the Batiste report.
25	Q. For two days, right?	25	A. Okay.

52 (Pages 202 to 205)

	Page 206		Page 208
1	Q. The Batiste report has been marked as	1	Q. (Indicating).
2	Exhibit Number 2.	2	MR. ANDERSON: 28th.
3	MR. THOMAS: Just for the record, I	3	A. Should be the 28th? I guess. We were
4	just got this late Monday night, and I've had a	4	all this was just taken out of the patient, I
5	chance to go through it a little. We'll reserve	5	believe, most recently, so we've been working on
6	on this. I know you disagree with that, but we	6	it.
7	may reserve to come back to ask more questions	7	BY MR. THOMAS:
8	about this report at a later time.	8	Q. Please understand I've got to mark
9	MR. ANDERSON: I mean I do object to	9	that one, too, just in case there's something
10	it, because there was an agreement made between	10	different.
11	Christy Jones and Rich Freese, and they agreed	11	A. I don't think you're going to be
12	that in the in order to help both sides,	12	finding any differences.
13	because everyone has a lot going on, that there	13	Q. I'm hopeful I won't.
14	was an agreement that you guys wanted to take	14	MR. ANDERSON: Not a lot I would bet
15	in fact, your attorneys from or the attorneys	15	on, but that one I will bet you there's
16	from Butler Snow I have to put this on the	16	absolutely no differences in that report other
17	record. If you're going to say you're going to	17	than that date.
18	reserve the right, I'm going to object and I'm	18	MR. THOMAS: Just for the record, I'm
19	going to put the reasons on.	19	marking as Exhibit Number 6 what Dr. Jordi had
20	Attorneys from Butler Snow reached out	20	in his file as being the final report for Linda
21	and said "any of the same experts who are going	21	Batiste dated October 30th, 2013. The one that
22	to be in both Lewis and Batiste, we'd like to	22	was produced to us that's been marked as
23	try to take their depositions at the same time	23	Exhibit 2 is October 28th.
24	so we don't have to come back and everybody fly	24	
25	around the country and do them at different	25	
	Page 207		Page 209
1	times." So we agreed to try to do that.	1	(Whereupon, Jordi Exhibit Number 6,
2	Also the agreement was that within 48	2	10/30/13 Final Report for Linda
3	hours of the depo we would get we said we'd	3	Batiste, was marked for
4	try within 48 hours of the depo, which we did,	4	identification.)
5	to send over the Batiste results.	5	BY MR. THOMAS:
6	And that was the agreement between the	6	Q. Mine is two-sided, and it's twice as
7	parties.	7	big as yours.
8	MR. THOMAS: I understand. I just	8	A. Yes, sir. No.
9	MR. ANDERSON: So I don't see how you	9	MR. ANDERSON: This is the rest of the
10	can then reserve your right after your side has	10	data.
11	already made an agreement, and we're doing it	11	A. This is the rest of it.
12	exactly the way your side wanted to.	12	BY MR. THOMAS:
13	MR. THOMAS: I'm not sure anybody	13	Q. Just for the record, I didn't realize
14	contemplated getting 278 pages, but I get it. I	14	there was a second set. So we have all of it,
15	just need to make that statement.	15	the data makes it twice as big as mine, as it
16	MR. ANDERSON: After getting a	16	should be. Thank you.
17	thousand on the others, I would think that would	17	Okay. Doctor, do you intend to rely
18	be reasonable. But go ahead with your	18	on the testing that you did in the Carolyn Lewis
19	questions.	19	case in support of your opinions in the Batiste
20	BY MR. THOMAS:	20	case?
21	Q. Doctor, when did you prepare the final	21	A. Yes. They're the same, the same
22	report of Linda Batiste? It's dated October	22	analyses, yes.
23	the 28th, 2013, would that be it?	23	Q. My question is a little different.
24 25	A. The final date I have is October 30th,	24	You did 22 plus, 22 or 23
. / h	2013. It's the same. You've got	25	A. 23.

53 (Pages 206 to 209)

1 2	Page 210		Page 212
	Q 23 explant analyses of other	1	same testing for Ms. Batiste as you did for the
	patients	2	analysis in Exhibit 1?
3	A. Yes.	3	A. Yes.
4	Q that are not included in your	4	Q. Is it appropriate to use the strike
5	analysis in the Batiste case.	5	that.
6	Do you intend as a part of your	6	Can we rely on your analysis in
7	opinions in Batiste to rely on your work that	7	Exhibit Number 1 with respect to the various
8	you did in Carolyn Lewis?	8	tests that we've talked about all day today in
9	MR. ANDERSON: I can tell you as his	9	understanding how you conducted the test for
10	attorney that's exactly what we're going to do,	10	Linda Batiste?
11	because there is no report requirement in Texas.	11	A. It was run the same way.
12	MR. THOMAS: Just asking.	12	Q. So any discussions that we've had
13	MR. ANDERSON: Let me just finish,	13	today about your methodology, your controls,
14	because he may not understand the legal	14	your results in the Carolyn Lewis report,
15	ramifications and what's going on as between a	15	Exhibit Number 1, would apply equally to the
16	state court requirement and a Federal Court	16	Linda Batiste report, Exhibit 2?
17	requirement. And there is no reporting	17	A. Yes.
18	requirement in Texas state court.	18	Q. All right. For Linda Batiste, you
19	But we did agree, even though there is	19	have a series of fiber mesh control samples.
20	no reporting requirement, that we would provide	20	Are these new mesh control samples different
21	data to make it easier for you guys to take a	21	from the mesh control samples you analyzed in
22	deposition, even though we don't have to provide	22	Carolyn Lewis?
23	a report. So we did that, and we gave it to you	23	(Witness reviewing documents.)
24	48 hours before the depo, like you asked.	24	A. They're the same.
25	So is he going to rely on all of his	25	BY MR. THOMAS:
	Page 211		Page 213
1	opinions in this case in Texas? You bet.	1	Q. Okay. And how can you tell they're
2	MR. THOMAS: Thank you.	2	the same; by the test numbers?
3	BY MR. THOMAS:	3	A. Same numbers. Table 1 on both.
4	Q. The testing that you did in the	4	Q. All right.
5	Batiste case differs from the testing that you	5	A. Page 6 versus Page 13 in the
6	did in the Carolyn Lewis case, I think.	6	Exhibit 1.
7	A. In what way?	7	Q. Not that this makes any difference to
8	Q. I don't think you did as much.	8	the ultimate test, do you know whether they were
9	A. Let me see.	9	all TVT Classics or TVT-Os?
10	(Witness reviewing document.)	10	MR. THOMAS: Or do you know the answer
	BY MR. THOMAS:	11	to that?
11	Q. I don't think you did the PYMS in	12	MR. ANDERSON: Three TVT, three TVT-O.
11 12			
11 12 13	Batiste.	13	MR. THOMAS: Thank you.
11 12 13 14	Batiste. A. Yeah, we did, it's right here	14	MR. THOMAS: Thank you. MR. ANDERSON: That's borne out in the
11 12 13 14 15	Batiste. A. Yeah, we did, it's right here (indicating).	14 15	MR. THOMAS: Thank you. MR. ANDERSON: That's borne out in the photographs in some of the extra stuff we
11 12 13 14 15 16	Batiste. A. Yeah, we did, it's right here (indicating). MR. ANDERSON: Page 44.	14 15 16	MR. THOMAS: Thank you. MR. ANDERSON: That's borne out in the photographs in some of the extra stuff we haven't gone through, for obvious reasons.
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11 12 13 14 15 16 17 18 19 20	Batiste. A. Yeah, we did, it's right here (indicating). MR. ANDERSON: Page 44. A. Page 44. BY MR. THOMAS: Q. That shows you how close we are. Thank you. I apologize.	14 15 16 17 18 19 20	MR. THOMAS: Thank you. MR. ANDERSON: That's borne out in the photographs in some of the extra stuff we haven't gone through, for obvious reasons. MR. THOMAS: Thank you. BY MR. THOMAS: Q. I'm looking at the "Summary of Results."
11 12 13 14 15 16 17 18 19 20 21	Batiste. A. Yeah, we did, it's right here (indicating). MR. ANDERSON: Page 44. A. Page 44. BY MR. THOMAS: Q. That shows you how close we are. Thank you. I apologize. A. We did the GPC.	14 15 16 17 18 19 20 21	MR. THOMAS: Thank you. MR. ANDERSON: That's borne out in the photographs in some of the extra stuff we haven't gone through, for obvious reasons. MR. THOMAS: Thank you. BY MR. THOMAS: Q. I'm looking at the "Summary of Results." A. Page, please?
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11 12 13 14 15 16 17 18 19 20 21 22 23	Batiste. A. Yeah, we did, it's right here (indicating). MR. ANDERSON: Page 44. A. Page 44. BY MR. THOMAS: Q. That shows you how close we are. Thank you. I apologize. A. We did the GPC. MR. ANDERSON: There's no question pending right now.	14 15 16 17 18 19 20 21 22 23	MR. THOMAS: Thank you. MR. ANDERSON: That's borne out in the photographs in some of the extra stuff we haven't gone through, for obvious reasons. MR. THOMAS: Thank you. BY MR. THOMAS: Q. I'm looking at the "Summary of Results." A. Page, please? Q. Page 3. It says "A series of mesh control samples and one explant sample received
11 12 13 14 15 16 17 18 19 20 21 22	Batiste. A. Yeah, we did, it's right here (indicating). MR. ANDERSON: Page 44. A. Page 44. BY MR. THOMAS: Q. That shows you how close we are. Thank you. I apologize. A. We did the GPC. MR. ANDERSON: There's no question	14 15 16 17 18 19 20 21 22	MR. THOMAS: Thank you. MR. ANDERSON: That's borne out in the photographs in some of the extra stuff we haven't gone through, for obvious reasons. MR. THOMAS: Thank you. BY MR. THOMAS: Q. I'm looking at the "Summary of Results." A. Page, please? Q. Page 3. It says "A series of mesh

54 (Pages 210 to 213)

	Page 214		Page 216
	_		
1	established that the mesh control samples are	1	scanning calorimetry analysis showed no change
2	the same control samples that you used for your	2	in crystallinity for the cracked explant sample
3	comparisons with Carolyn Lewis in Exhibit 1,	3	compared with the control samples."
4	correct?	4	What does that mean?
5	A. Correct.	5	A. That means that the crystallinity
6	Q. And the explant sample is for Linda	6	didn't change, and the sample won't be more
7	Batiste who is the Plaintiff in the Texas	7	likely to be subjected to environmental stress
8	action, right?	8	cracking.
9	A. Correct.	9	Q. Okay.
10	Q. "Upon handling, it was observed that	10	A. Any damage we see would have to be
11	the explant sample showed some decreased	11	oxidative type damage.
12	elasticity as compared to the control fiber mesh	12	Q. So can we eliminate from the Linda
13	samples."	13	Batiste analysis any environmental stress
14	Again, this represents the same	14	cracking?
15	reporting that you made in the Carolyn Lewis	15	A. Yes, you can eliminate the DSC data if
16	case about your handling of the mesh explant as	16	you want, because it's going to say there's no
17	compared to the control?	17	change.
18	A. That's right.	18	Q. Okay. So you have no molecular weight
19	Q. And do you have any recollection in	19	change and no DSC change?
20	the Batiste matter for comparing the explant to	20	A. That's correct. In this one sample.
21	the formalin control samples?	21	Q. I understand.
22	A. Formalin control sample, no, I don't.	22	Do you know when Ms. Batiste had her
23	I felt the explanted material was rigid, and the	23	surgery to remove her explant?
24	pristine felt very friable.	24	A. I don't know the exact date, no. It
25	Q. Okay. Next paragraph, "Cracking in	25	was recent, within the last couple weeks,
	Page 215		Page 217
1	Page 215 the explant sample was observed to propagate in	1	Page 217 something like that.
1 2	_	1 2	
	the explant sample was observed to propagate in		something like that.
2	the explant sample was observed to propagate in a direction perpendicular to the fiber draw	2	something like that. Q. Last sentence of the last paragraph
2	the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the	2 3	something like that. Q. Last sentence of the last paragraph before you get to the table of contents, "It was
2 3 4	the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the fiber surface."	2 3 4	something like that. Q. Last sentence of the last paragraph before you get to the table of contents, "It was found that the explant sample showed significantly less signal for the antioxidants as compared to the control sample, under 2
2 3 4 5	the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the fiber surface." That's the same finding that you made	2 3 4 5	something like that. Q. Last sentence of the last paragraph before you get to the table of contents, "It was found that the explant sample showed significantly less signal for the antioxidants
2 3 4 5 6 7 8	the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the fiber surface." That's the same finding that you made for Carolyn Lewis? A. Yes, that will be reflected in the photos, SEM graphs.	2 3 4 5 6	something like that. Q. Last sentence of the last paragraph before you get to the table of contents, "It was found that the explant sample showed significantly less signal for the antioxidants as compared to the control sample, under 2 percent for Santonox R and dilauryl thiodipropionate."
2 3 4 5 6 7 8 9	the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the fiber surface." That's the same finding that you made for Carolyn Lewis? A. Yes, that will be reflected in the photos, SEM graphs. Q. "Analysis" I'm down in next	2 3 4 5 6 7	something like that. Q. Last sentence of the last paragraph before you get to the table of contents, "It was found that the explant sample showed significantly less signal for the antioxidants as compared to the control sample, under 2 percent for Santonox R and dilauryl thiodipropionate." A. That's right.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the fiber surface." That's the same finding that you made for Carolyn Lewis? A. Yes, that will be reflected in the photos, SEM graphs. Q. "Analysis" I'm down in next paragraph now "analysis of the explanted fiber mesh by GPC-HT indicated that large scale molecular weight degradation had not occurred in the samples." The same finding that you had in Carolyn Lewis? A. Absolutely. Q. And when you say "large scale," the fact of the matter is you found no significant change in molecular weight; true? A. In this sample we didn't see a change in the oh, molecular weight you're saying? Q. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	something like that. Q. Last sentence of the last paragraph before you get to the table of contents, "It was found that the explant sample showed significantly less signal for the antioxidants as compared to the control sample, under 2 percent for Santonox R and dilauryl thiodipropionate." A. That's right. Q. What does that mean? A. That means that 98 percent of it was gone. Q. Got it. A. This time we know for a fact, because the surgery was just performed, that it wasn't sitting in Steelgate for months. Q. Okay. A. Because it was the surgery was performed, and it was immediately forwarded to us as rapidly as possible. So it would have just been a matter of days at room temperature before we got it and could start our work, as
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the fiber surface." That's the same finding that you made for Carolyn Lewis? A. Yes, that will be reflected in the photos, SEM graphs. Q. "Analysis" I'm down in next paragraph now "analysis of the explanted fiber mesh by GPC-HT indicated that large scale molecular weight degradation had not occurred in the samples." The same finding that you had in Carolyn Lewis? A. Absolutely. Q. And when you say "large scale," the fact of the matter is you found no significant change in molecular weight; true? A. In this sample we didn't see a change in the oh, molecular weight you're saying? Q. Yes. A. No, no change in molecular weight.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	something like that. Q. Last sentence of the last paragraph before you get to the table of contents, "It was found that the explant sample showed significantly less signal for the antioxidants as compared to the control sample, under 2 percent for Santonox R and dilauryl thiodipropionate." A. That's right. Q. What does that mean? A. That means that 98 percent of it was gone. Q. Got it. A. This time we know for a fact, because the surgery was just performed, that it wasn't sitting in Steelgate for months. Q. Okay. A. Because it was the surgery was performed, and it was immediately forwarded to us as rapidly as possible. So it would have just been a matter of days at room temperature before we got it and could start our work, as opposed to I really didn't know how long the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the explant sample was observed to propagate in a direction perpendicular to the fiber draw direction. It was noted to be primarily on the fiber surface." That's the same finding that you made for Carolyn Lewis? A. Yes, that will be reflected in the photos, SEM graphs. Q. "Analysis" I'm down in next paragraph now "analysis of the explanted fiber mesh by GPC-HT indicated that large scale molecular weight degradation had not occurred in the samples." The same finding that you had in Carolyn Lewis? A. Absolutely. Q. And when you say "large scale," the fact of the matter is you found no significant change in molecular weight; true? A. In this sample we didn't see a change in the oh, molecular weight you're saying? Q. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	something like that. Q. Last sentence of the last paragraph before you get to the table of contents, "It was found that the explant sample showed significantly less signal for the antioxidants as compared to the control sample, under 2 percent for Santonox R and dilauryl thiodipropionate." A. That's right. Q. What does that mean? A. That means that 98 percent of it was gone. Q. Got it. A. This time we know for a fact, because the surgery was just performed, that it wasn't sitting in Steelgate for months. Q. Okay. A. Because it was the surgery was performed, and it was immediately forwarded to us as rapidly as possible. So it would have just been a matter of days at room temperature before we got it and could start our work, as

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	Page 218		Page 220
1	short.	1	Q. And the others would be reflected in
2	Q. Do you know the percentage of	2	the lab notebooks?
3	formaldehyde in which the material was stored?	3	A. Lab notebooks.
4	A. I do not.	4	Q. And billings?
5	Q. Did you follow the same sample	5	A. Billings.
6	preparation methods we've described?	6	Q. Do you know the answer to the question
7	A. Yes, in terms of removal of tissue and	7	about why Page 6 shows in Table 1 the control
8	using forceps and disposable	8	sample analysis chart is different than it is in
9	Q. Why did you choose the control samples	9	Carolyn Lewis which appears on Page 13?
10	that you did in Table 1 on Page 6? Is that the	10	A. I'd have to refer to the lab
11	same ones that you chose before?	11	notebooks. Maybe it's in the lab notebooks. Do
12	A. Same ones, yes.	12	you want me to do that?
13	Q. The reason why I asked is because	13	Q. Well, to the extent that there's other
14	Table 1 on Page 13 shows a number of additional	14	testing well, strike that. We'll come back
15	tests being conducted on the other controls.	15	to that.
16	A. On page what?	16	Look at your lab notebooks and see if
17	Q. Right here. Compare this chart to	17	you did new testing.
18	this chart. They should be the same, shouldn't	18	A. Let's see. That would have had to
19	they?	19	have been
20	MR. ANDERSON: Yes, they are.	20	MR. ANDERSON: That's the old ones.
21		21	(Witness reviewing documents.)
22	MR. THOMAS: Right here. All this data is not on this chart.	22	A. 10/29.
23		23	
24	MR. ANDERSON: Oh, the data, I thought	24	MR. ANDERSON: Here you go. This is Batiste.
25	you said the tests that were run.	25	
23	A. They weren't. That means that these	25	A. Scalpel yeah, that's Batiste.
	Page 219		Page 221
1	were run again. And the rest of these were not	1	MR. ANDERSON: You're looking to see
2	run again.	2	about the OM and SEM, I think.
3	BY MR. THOMAS:	3	MR. THOMAS: The reason why the
4	Q. So	4	difference of charts.
5	A. We did another FTIR micro, we did	5	MR. ANDERSON: Yes.
6	another DSC, another GPCT.	6	(Witness reviewing documents.)
7	Q. Does this mean you repeated the test	7	A. So this is all Batiste. There's no
8	for the first two categories, the OM and the	8	indication of any reruns of those standards, of
9	SEM?	9	the controls in here, so
10	A. I need to see the billing.	10	BY MR. THOMAS:
11	Q. How much of this testing did you do	11	Q. Is it just an omission?
12	yourself; any of it?	12	A. I think it may just be an omission.
13	A. I don't these days I don't do much	13	Q. Okay.
14	myself. I just supervise the lab personnel.	14	A. 3422128.
15	Q. Is it fair to understand that for both	15	Yeah, I think X is up here, that's
16	Linda Batiste and Carolyn Lewis that others did	16	correct. I think it's an omission. We'll have
17	the work for you and reported to you and	17	to correct the table.
18	prepared your report, and you're testifying	18	Q. Okay.
19	based on other	19	A. It would have been the same data.
20	A. I prepared the report. They gave me	20	Q. Do you remember, given that this
21	their individual results.	21	report is dated today
22	Q. Okay. And you are preparing the	22	A. I'll tell you what we can do. We can
23	report and testifying based on the work of	23	pick a control sample here and just see if the
24	others?	24	picture is identical.
25	A. Correct.	25	Q. Okay.

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	Page 222		Page 224
1	A. That will be a good indication.	1	now any findings different for Linda Batiste
2	I'm sorry, can we go off the record a	2	about your observations of the mesh?
3	second?	3	A. Anything different?
4	MR. ANDERSON: We don't have to go off	4	Q. From what you found with Carolyn
5	the record. Just don't talk while you're	5	Lewis.
6	looking.	6	A. Oh, sure, we've already specified one
7	(Witness reviewing document.)	7	difference. The DSC didn't show
8	A. That picture looks identical, Figure 4	8	Q. That was a bad question.
9	looks identical to Figure 5 here, which is the	9	A the decreased Delta H.
10	same control.	10	Q. Let me start over again. Strike that.
11	BY MR. THOMAS:	11	I better do it the right way.
12	Q. Just for the record, you're referring	12	Let's go to Page 8 excuse me. I'm
13	to Exhibit Number 1, Page 20, Figure 4, to	13	sorry. Page 14, Figure 8.
14	Exhibit Number 2, Page 12, Figure 5?	14	In a number of places in Exhibits 1
15	A. Right.	15	and 2 there will be figures with numbers that
16	Q. So it's your best judgment, based upon	16	are shown on there. Here on Figure 8 there's
17	your review of those documents, that you're	17	Figures 1, 2, 3 and 4 in red on the mesh.
18	using the same control information for both	18	Do these represent places where, what,
19	studies?	19	scanning electron microscopy was conducted, or
20	A. Here would be a more definitive	20	do you know?
21	picture.	21	A. I don't know.
22	MR. ANDERSON: Just answer his	22	Q. So like on the next page, on Page 15,
23	question.	23	Figure 10, there are red numbers 1, 2, 3, 4. Do
24	A. I'm sorry.	24	you know what those represent?
25	BY MR. THOMAS:	25	A. Well, I can look at the EDX and see if
	Page 223		Page 225
1	Q. So it's your best judgment, based upon	1	the numbers if we have four sites on EDX,
2	your review of those documents, you're using the	2	that would be the likely if there's going to
3	same control information for both studies?	3	be any correlation, that's what it would be, go
4	A. It looks that way. 159, you see	4	find this sample number.
5	MR. ANDERSON: Do you feel like you've	5	Q. When you say "EDX," the data that you
6	answered his question that you're using the same	6	have in your EDX analysis?
7	controls?	7	A. Yeah. But I don't know, with a
8	THE WITNESS: Yes.	8	control like this, I don't know why that would
9	MR. ANDERSON: Okay. Then we'll move	9	it would make no sense, so I doubt it. But
10	on to the next one.	10	we can check one sample.
11	BY MR. THOMAS:	11	Q. Check to make sure.
12	Q. Now if you go to Page 9, Page 9,	12	A. 13161.
13	Figure 3, does this depict the Batiste mesh as	13	It's not here. I don't know what it
14	first received by you and then separated into	14	means.
15	tissue and mesh as you did with the mesh in	15	Q. Okay. And just so we're clear, if you
16	Carolyn Lewis?	16	go back to Carolyn Lewis, let's go to Page 24 of
17 18	A. It does.	17	Carolyn Lewis. Figure 11, again samples 13162,
	Q. And did you follow the same	18	and there are numbers in red, 1, 2, 3, 4, do you know what those represent?
	procedures?		
19	procedures?	19	*
19 20	A. We did.	20	A. No, I do not.
19 20 21	A. We did. Q. And did Mr	20 21	A. No, I do not.Q. Okay. If you go to Page 18, please,
19 20 21 22	A. We did.Q. And did MrA. Adi Kulcarni. Yes, I watched him do	20 21 22	A. No, I do not. Q. Okay. If you go to Page 18, please, of Batiste, Exhibit 2, Figure 16. Is this the
19 20 21 22 23	A. We did. Q. And did Mr A. Adi Kulcarni. Yes, I watched him do it.	20 21 22 23	A. No, I do not. Q. Okay. If you go to Page 18, please, of Batiste, Exhibit 2, Figure 16. Is this the photograph strike that.
19 20 21 22	A. We did.Q. And did MrA. Adi Kulcarni. Yes, I watched him do	20 21 22	A. No, I do not. Q. Okay. If you go to Page 18, please, of Batiste, Exhibit 2, Figure 16. Is this the

57 (Pages 222 to 225)

1 Exhibit Number 1 as not cracked, moderately 2 cracked, or cracked, where does this fit? 3 A. These photos here I would call 4 severely cracked. 4 severely cracked. 5 Q. Considerably cracked? 6 A. Considerably or severely, you could 7 use either word. 8 Q. Okay. Let me ask this question. 9 You've used a number of different ways 10 today to characterize the cracking that you've 11 seen, and you've broken them down into 12 categories in different places in your report. 13 What categories of cracking do you 14 deem to be relevant to your analysis on a 15 comparative basis across these mesh? 16 MR. ANDERSON: Objection. Asked and 17 answered way long ago. 18 But answer the question again. 19 A. Minimally, not cracked, minimally, 10 Is cracked more than the 411 sample. 2 Q. So on Page 38, sample 13412, you describe as being moderately cracked. 4 What is it about Exhibit 40 on Page 38 6 of Exhibit Number I that qualifies that as moderately cracked? 7 A. Particularly on the right side of the picture, the cracks are somewhat weak looking, they're not deep into the sample. 10 Now, there are a couple of places 11 there, this is what makes this so difficult, there are a couple of places on the left side where I would call it certainly more severe 14 deem to be relevant to your analysis on a 15 comparative basis across these mesh? 16 MR. ANDERSON: Objection. Asked and 17 answered way long ago. 18 But answer the question again. 19 A. Minimally, not cracked, minimally, 19 order.		Page 226		Page 228
2 A. Photograph of not the SEM, but just a regular optical microscope of the fiber mesh with tissue imbedded in it. Q. And with tissue imbedded in it. Q. And was mphification SEM. Q. Of the same thing that's depicted in Figure -	1	O What is that?	1	show you that one a while ago in the other set
regular optical microscope of the fiber mesh with tissue imbedded in it. Q. And what is Figure 17? A. That's a low amplification SEM. Figure Q. Of the same thing that's depicted in Figure 17 the Is what's depicted in Figure 17 the Is what's depicted in Figure 16, just by different medium? A. Ry different methods. C. Methods. A. SEM versus optical. C. A. SEM versus optical. C. A. Al looks like greatly cracked material where some of the material has actually flaked me. C. In your description that you used in Fagure 22 on In your description that you used in C. Considerably cracked, or cracked, where does this fit? C. Considerably or severely, you could use either word. C. Considerably or severely, you could use either word. C. Okay. Let me ask this question. You've used a number of different ways today to characterize the cracking that you've seem to be relevant to your analysis on a comparative basis across these mesh? Comparative basis across these mesh? A. Minimally, not cracked, minimally, A. Minim				
with tissue imbedded in it. Q. And what is Figure 17? A. Thar's a low amplification SEM. Q. Of the same thing that's depicted in Figure 17 the same thing that's depicted in Figure 16, just by different medium? A. By different methods. Q. Methods. A. By different methods. Q. And a you look at Figure 22 on Page 21, and Figure 23, how would you describe what you see in Figure 22? A. It looks like greatly cracked material where some of the material has actually flaked off, getting clear under regions underneath. Q. In your cast of characters — excuse me. In your description that you used in Page 217 Exhibit Number 1 as not cracked, moderately cracked, or cracked, where does this fit? A. Considerably cracked? A. Think it was 411. Yes, 411. That's minimally. A. It link it was 411. Yes, 411. That's minimally. A. It link it was 411. Yes, 411. That's minimally. A. It link it was 411. Yes, 411. That's minimally. A. That's in Exhibit 1. And that's your visual observations, you conclude that the cracking shown on Page 37 fair? A. Fair. A. Fair. A. Fair. A. That might be moderately cracked? A. These are arbitrary categories, of course, that's why it's very difficult to put absolute numbers on these. But that certainly absolute numbers on these. But that certainly absolute numbers on these. But that certainly describe as being moderately cracked. A. Chating the material has a fair? A. That might be moderately cracked? A. That might be moderately cracked? A. That might be moderately cracked? A. Tha				
5 Q. And what is Figure 17? A. That's a low amplification SEM. O. Of the same thing that's depicted in Figure Figure A. Right. O. Excuse me. Is what's depicted in Figure 16, just by different medium? A. By different methods. A. SEM versus optical. O. And as you look at Figure 22 on Page 21, and Figure 23, how would you describe what you see in Figure 22? A. It looks like greatly cracked material where some of the material has actually flaked off, getting clear under regions underneath. Description that you used in Page 227 Exhibit Number 1 as not cracked, moderately cracked, or cracked, where does this fit? A. Considerably cracked? A. Considerably or severely, you could use either word. O. Okay. Let me ask this question. You've used a number of different ways today to characterize the cracking thay ou've seen to day to characterize the cracking do you deem to be relevant to your analysis on a comparative basis across these mesh? A. Minimally, not cracked, minimally, A. Minimally, not cracked, minimally, Seen and what is Figure 2 in A. A. A. It hink it was 411. Yes, 411. That's minimally. A. It hink it was 411. Yes, 411. That's minimally. A. It hink it was 411. Yes, 411. That's minimally. A. A. That's in Exhibit 1. And that's your visual observations, you conclude that the cracking shown on Page 37 in Figure 38, sample 13411, is minimal cracking; fair? A. Fair. Q. All right. What is in was 411. Yes, 411. That's minimally. A. That's exactly right. A. That's exactly right. A. That's exactly right. A. That's exactly right. A. That's mactly your tisual observations, you conclude that the cracking shown on Page 37 in Figure 38, sample 13411, is minimal cracking; fair? A. Fair. Q. All right. What is in was 411. Yes, 411. That's minimally. A. That's exactly right.				
6 Å. That's a low amplification SEM. 7 Q. Of the same thing that's depicted in Figure - 8 9 Figure - 8 10 Q. Excuse me. 10 11 Is what's depicted in Figure 17 the same thing that's depicted in Figure 16, just by different medium? 13 12 different medium? 13 13 different medium? 14 14 A. By different methods. 15 15 Q. Methods. 16 16 A. SEM versus optical. 16 17 Q. And as you look at Figure 22 on 19 18 Page 21, and Figure 23, how would you describe what you see in Figure 22? 19 20 A. It looks like greatly cracked material where some of the material has actually flaked 21 23 where some of the material has actually flaked 22 off, getting clear under regions underneath. 23 24 me. 24 me. 24 25 In your cast of characters - excuse 24 me. 24 25 Exhibit Number 1 as not cracked, moderately 27 26 A. That's in Exhibit 1. And that's your visual observations, you conclude that the cracking shown on Page 37 in Figure 38, sample 13411, is minimal cracking; fair? A. Fair. Q. All right. What is moderately cracked? A. That might was 41. Yes, 411. That's minimally. 20 Q. That's in Exhibit 1. And that's your visual observations, you conclude that the cracking shown on Page 37 in Figure 38, sample 13411, is minimal cracking; fair? A. Fair. Q. All right. What is moderately cracked? A. That might was 41. Yes, 411. That's minimally. A off that's your visual observations, you conclude that the cracking shown on Page 37 in Figure 38, sample 13411, is minimal cracking; fair? A. Fair. Q. All right. What is moderately cracked? A. That might was 41. Yes, 411. That's minimally.				
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A. Right. Q. Excuse me. Is what's depicted in Figure 17 the same thing that's depicted in Figure 16, just by different medium? A. By different methods. Q. Methods. Q. Methods. Q. And as you look at Figure 22 on Page 21, and Figure 23, how would you describe what you see in Figure 22? A. It looks like greatly cracked material where some of the material has actually flaked off, getting clear under regions underneath. Q. In your cast of characters — excuse me. In your description that you used in Page 227 Exhibit Number 1 as not cracked, moderately cracked, or cracked, where does this fit? A. These photos here I would call severely cracked. Q. Considerably cracked? A. Considerably cracked. Q. Okay. Let me ask this question. You've used a number of different ways today to characterize the cracking that you've seen, and you've broken them down into categories in different places in your report. What categories of cracking do you describe answered way long ago. But answer the question again. A. Minimally, not cracked, minimally, A. Minimally, not cracked, minimally, Q. So on Page 38, sample 13411, is minimal cracking; fair? A. Fair. A. That is figure 13, hard that's your visual observations, you conclude that the cracking shown on Page 37 in Figure 38, sample 13411, is minimal cracking; fair? A. Fair. A. Fair. A. Fair. A. That might be moderately cracked? A. That might be moderate right there (indicating). Q. What page? A. These are arbitrary categories, of course, that's why it's very difficult to put absolute numbers on these. But that certainly on Page 38 of Exhibit Number 1 that qualifies that as moderately cracked. What categories of cracking do you describe as being moderately cracked. A. Paricularly on the right side of the picture, the cracks are somewhat weak looking, they re not deep into the sample. Now, there are a couple of places on the left side where I would call it certainly more severe cracking, what they're				
10 Q. Excuse me. 10 Q. That's in Exhibit 1.				- 1
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14 A. By different methods. 15 Q. Methods. 16 A. SEM versus optical. 17 Q. And as you look at Figure 22 on 18 Page 21, and Figure 22? 19 what you see in Figure 22? 20 A. It looks like greatly cracked material 21 where some of the material has actually flaked 22 off, getting clear under regions underneath. 23 Q. In your cast of characters excuse 24 me. 25 In your description that you used in Page 227 Exhibit Number 1 as not cracked, moderately 21 cracked, or cracked, where does this fit? 22 cracked, or cracked, where does this fit? 23 A. These photos here I would call 24 seeverly cracked. 25 Q. Considerably cracked? 26 A. Considerably or severely, you could 27 use either word. 28 Q. Okay. Let me ask this question. 29 You've used a number of different ways 20 today to characterize the cracking that you've 21 seen, and you've broken them down into categories in different places in your report. 29 MR. ANDERSON: Objection. Asked and answered way long ago. 20 Mat page? 21 A. 38. 22 Q. Page 38. Are we in Exhibit 1? 23 A. These are arbitrary categories, of course, that's why it's very difficult to put absolute numbers on these. But that certainly 29 Page 227 20 So on Page 38, sample 13412, you describe as being moderately cracked. 30 G. Stabilit Number 1 that qualifies that as moderately cracked? 41 Sexplain the moderate right there 42 (indicating). 42 C. What page? 43 A. These are arbitrary categories, of course, that's why it's very difficult to put absolute numbers on these. But that certainly 45 describe as being moderately cracked. 46 What is it about Exhibit 40 on Page 38 of Exhibit Number 1 that qualifies that as moderately cracked? 57 A. Particularly on the right side of the picture, the cracks are somewhat weak looking, they're not deep into the sample. 58 Now, there are a couple of places on the left side where I would call it certainly more severe cracking, what they're not they don't represent a large portion of the surface. 69 Q. So the cracks that you're referring to are less than a micron in widt				
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120 moderatery, and then major cracking, or 120 Q. And for Ms. Batiste on Page 21.	20	moderately, and then major cracking, or	20	Q. And for Ms. Batiste on Page 21,
21 extensive cracking. 21 Figures 21 and 23, how would you describe that		•		
22 BY MR. THOMAS: 22 cracking?				
Q. What qualifies how would you 23 A. Page what now?	. – –			
		Q. What qualifies now would you		in rage what now.
A. Where I just would see like I did 25 A. Well, you have to look at several of	23	describe something that's minimally cracked?		

58 (Pages 226 to 229)

	Page 230		Page 232
1	these photos taken together to get kind of like	1	A. Somewhat.
2	an average.	2	Q. And that's for severe cracking?
3	Q. Okay.	3	A. Well, it's severe. If I just saw one
4	A. If I look at if I look at Page 20,	4	of those cracks and nothing else and it was
5	I might call it moderate. But if I look at	5	clean everywhere else, like if all I saw was
6	Page 21, these are different regions of the same	6	this
7	sample, I'm going to call that severe, because	7	Q. What you're doing now is you're
8	of flaking.	8	A. I'm covering up the cracks. But I'm
9	Q. Is it the flaking that makes it	9	showing you the rest of the fiber. In this case
10	severe?	10	the whole fiber isn't damaged, just the left
11	A. Flaking, yeah, because the actual	11	side.
12	polymer is degraded so badly it's coming off the	12	Q. That's Figure 26?
13	surface.	13	A. 22 Figure 25, sorry.
14	Q. All right.	14	Q. Figure 25 on Page 22 of Exhibit 2?
15	A. It's also the depth. If you want to	15	A. Correct.
16	see the depth, Page 23 shows you the deep	16	Q. Okay. Figure 25 on Page 22 of
17	cracking that hasn't yet flaked, but you can see	17	Exhibit 2, the cracks that you see on the left
18	it's just dying to flake off on Page 23.	18	side, again are 1 to 3 microns wide. That's 600
19	Q. Just so the record is clear, that's a	19	times magnification, that's even higher?
20	higher magnification than the early ones? It's	20	A. But you've got the scale here of
21	450 times, right? Page 23 is 400 times, is that	21	Q. You changed the page again on me.
22	right?	22	Which one are you looking at now?
23	A. Yeah. So I would call this moderate	23	A. Page 23, 26.
24	to severe.	24	Q. Okay. Figure
25	Q. And is it the number of cracks?	25	A. 450X.
	Page 231		Page 233
1	A. Number of cracks, the depth of the	1	Q. Page 23, 450X, Figure 26.
2	cracks, and whether or not it's flaked all enter	2	A. So that crack there on the the big
3	into the flaking tends to	3	crack in the middle of the left side of that
4	Q. How are you able to measure the depth	4	picture looking at the scale has got to be on
5	of the cracks? Or is this just by total	5	the order of
6	eyeballing it?	6	Q. 5 microns?
7	A. It's total eyeballing at this point,	7	A 5-micron, something like that.
8	because you can't really until you see the	8	Q. No way to tell from this how deep it
9	pieces come off, and then they look like they're	9	is?
10	several microns.	10	A. You can tell from the now you can
11	Q. As a practical matter, isn't it	11	tell because it's bent upwards. The actual
12	impossible to measure the depths of these cracks	12	thickness of the polypropylene piece that's
13	because they're so small?	13	about to break off looks like it's 1 to
14	A. Well, to get an accurate measurement,	14	2 microns.
15	right, looking at this photograph I can't tell	15	Q. Okay. But the depth there is not
16	you exactly how many. But the depth is at least	16	going to be any more than five microns?
17	as great, it would appear here, as the width.	17	A. No.
18	Q. So a little less than a micron?	18	Q. Probably less?
19	A. Well, I would say that's more like 2	19	A. On that order, yes.
20	microns, that crack.	20	Q. Okay. So that's severe cracking?
21	Q. Okay.	21	A. Yes, because it runs, covers the
22	A. Some of this one might be 2 to 3,	22	entire
23	some of them are 1. They're variable.	23	Q. Okay. Let's go to Page 29, Figure 33.
24	Q. Okay. And you would expect a similar	24 25	You're conducting the SEM-EDX analysis
25	depth to that 1 to 3 microns?		here, correct?

59 (Pages 230 to 233)

	Page 234		Page 236
1	A. Yes. Correct.	1	this peak here, that's in the region that isn't
2	Q. And how would you describe the	2	cracked.
3	cracking that you see in Figure 33?	3	Q. My question is not what the proof of
4	A. Moderate in that particular piece.	4	it is. My question is what caused it.
5	Q. All right. And Spectrum 2 and	5	What caused the oxidation?
6	Spectrum 3 are shown.	6	A. What caused the oxidation. Well, that
7	Is there a Spectrum 1?	7	would probably be due to the inflammation, among
8	A. No. Usually just shows two pieces, I	8	other things, that's in the human body. If the
9	don't know why we had three on here.	9	material isn't protected by antioxidants and
10	Q. Do you usually start numbering at 2?	10	it's exposed to macrophages and hydrogen
11	A. I don't know why that was done. It's	11	peroxide and so on, if there was inflammation,
12	2, he may have had a 1 somewhere else, or just	12	and shards were coming off the particle and
13	didn't renumber them.	13	inflammation is caused to increase that
14	Q. If there's a 1, it doesn't show up on	14	Q. Are you guessing, or is that your
15	the data that appears here, correct?	15	opinion?
16	A. Right. The box and the number	16	A. That's published literature.
17	correlates with the spectrum you see below.	17	Q. It's your opinion that published
18	Q. Right.	18	literature stands for the proposition that in
19	What's the difference between 34 and	19	the face of inflammation, that polypropylene
20	35?	20	mesh without antioxidants will degrade?
21	A. Just a scale-up.	21	A. Yes.
22	Q. Okay.	22	Q. And what literature is that?
23	A. So we can see the minor elements	23	A. Well, it goes back to
24	better.	24	Q. Is that the Liebert article?
25	Q. I see.	25	A. Liebert article, it goes back to
	- 00-		
	Page 235		Page 237
1		1	
1 2	DSC, we decided there was no change,	1 2	Oswald and Turi article, as early as '65.
2	DSC, we decided there was no change, so there's no evidence of environmental stress	1 2 3	Oswald and Turi article, as early as '65. Q. Okay.
2	DSC, we decided there was no change, so there's no evidence of environmental stress cracking?	2	Oswald and Turi article, as early as '65.
2 3 4	DSC, we decided there was no change, so there's no evidence of environmental stress cracking? A. Let me just look at the numbers, but I	2	Oswald and Turi article, as early as '65. Q. Okay. A. Williams talks about it in a number of articles.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	DSC, we decided there was no change, so there's no evidence of environmental stress cracking? A. Let me just look at the numbers, but I believe that's correct. (Witness reviewing document.) A. That's correct. BY MR. THOMAS: Q. So any oxidation that's occurringstrike that. So any of the cracks that we see in Linda Batiste is going to be due to straight oxidation? A. I believe that's correct. Q. And do you know what caused the oxidation in Linda Batiste's mesh? A. Well, one cause would be the lack of antioxidant in the fiber, if we find that, which we have to go look at the LCMS analysis primarily. The other would be the IR results for	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Oswald and Turi article, as early as '65. Q. Okay. A. Williams talks about it in a number of articles. Q. It's ultimately premised on the suggestion that the antioxidants in the Ethicon mesh have leached out and are gone, correct? A. Correct. Q. Right. And it's only if the antioxidants are leached out and gone that your theory is correct? A. I don't know that it would mean you couldn't oxidize polypropylene even in the presence of antioxidants. You certainly can. But it retards it. Q. But you've not studied that question. Your theory and opinion is that the antioxidants have leached out, therefore the mesh is degraded? That's your opinion to a reasonable degree of certainty?
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Page 238 Page 240 see if we see a lack of. 1 1 paragraph, "After you don't find a difference in 2 2 Q. I understand. molecular weight, the environmental stress 3 3 cracking mechanism does not require a decrease But that's your opinion to a 4 4 reasonable degree of scientific certainty how in molecular weight." 5 this degradation occurred; that is, that the 5 I think we've already decided that the 6 antioxidants leached out leaving the mesh 6 mesh -- any mesh degradation for Ms. Batiste is 7 7 not due to environmental stress cracking; fair? defenseless, and that is the reason why the mesh 8 degraded? 8 A. Right. 9 9 Q. Okay. A. Yes. 10 Q. Page 34 --10 A. So that's why I state we observed 11 A. Yes, sir. cracking in the explant samples due to oxidation 11 12 Q. -- on Exhibit 2. 12 in the fiber surface, in this particular sample. 13 This same value is in Exhibit 1, the 13 Q. In the PYMS analysis on Page 34. 14 A. Page 34? 14 typical value for the melt point of 15 polypropylene? 15 Q. I'm sorry, 44. Thank you. 16 16 A. Where are you? A. Okav. 17 Q. I'm right in the middle of the page on 17 Q. Am I correct that there's no analysis 18 18 Page 34. of the Santonox antioxidant? 19 A. 34. Okay. Right. 19 A. Right. 20 Q. Is it your opinion that the typical 20 Q. Why not? value for polypropylene melting is 175 degrees 21 21 A. As I mentioned this morning, in PYMS 22 22 when you -- if you'll look at Page 45, Figure C? 23 23 46, the antioxidants, you'll see a large --A. Again, that comes out of the book we 24 looked at earlier this morning, Turi. 24 you'll see the control is the blue, and you'll 25 Q. Do you know whether that is the 25 see a large red peak righter blue is eluting. Page 239 Page 241 1 typical melt point for the polypropylene mesh 1 What that is mostly is polypropylene fragment 2 that Ethicon manufactured and sold? 2 ions, and it was overwhelming the signal for 3 A. No. We measured, we measured that as 3 Santonox R, so we really couldn't get an 4 well. That's the controls. It's 165-ish. 4 accurate reading. 5 Q. Okay. My point is; you're not 5 Q. Tell me what that means. I don't know 6 how that works. I don't understand. б suggesting because it's 165 instead of 175 from 7 7 the literature that it's more susceptible to A. Well, in LCMS you extract the environmental stress cracking or degradation, 8 8 additives, and then you shoot a solution of the 9 are you? 9 extract, so you don't have the polymer to worry A. I'm suggesting it's less crystalline. 10 about at all. 10 11 Q. Okay. Are you suggesting it's more 11 In PYMS you put the entire sample in, 12 the solid polypropylene piece, or a bit of 12 susceptible to environmental stress cracking 13 because --13 actual fiber, and then you burn it basically, 14 14 A. Than the native pellet polypropylene pyrolize it, and then the pieces go into the GC 15 from which the fiber was manufactured, yes, I 15 system column and get separated. But there are 16 sometimes hundreds of thousands of pieces, and 16 am. 17 sometimes for materials you want to analyze they 17 Q. And are you suggesting that it's more 18 susceptible to oxidation because its melting 18 just get overwhelmed, the material I want to 19 19 point is 165 as opposed to 175 and 80 analyze for is overwhelmed by the background is 20 polypropylene pellets? 20 what it's called. 21 21 A. Yes. So any estimate we would have made Q. Page 43 in your molecular weight 22 22 here, we would have got a large peak, it doesn't 23 analysis. 23 mean anything because it's got all these other 24 ions in it, which just is flooding the system in 24 A. Okay. 25 25 Q. It says in the middle of the that particular time point.

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1	Page 242		Page 244
	Now, for the other antioxidate, the	1	Q. All right. At this time for the LCMS
2	lauryl thiodipropionate	2	test beginning on Page 46, there's no formalin
3	Q. Let me just interrupt for a minute.	3	control data, is there?
4	Could you have changed your test or	4	A. No.
5	changed your materials to test again for	5	Q. So the tests that you conducted in
6	Santonox in an effort to capture the	6	LCMS would not show the extent to which formalin
7	concentration of Santonox?	7	may have confounded your findings?
8	A. You can run single ion, extracted ion	8	A. For the Santonox R, that would be
9	chromatography, we call it, that helps. In this	9	true. But for the lauryl thiodipropionate, the
10	case it didn't help enough.	10	standards we've already run clearly were not
11	Q. Why does it work in the Carolyn Lewis	11	extracted by the formalin.
12	case for all the samples that you've tested	12	Q. You didn't do a formalin control test
13	there, but doesn't for Linda Batiste?	13	for Linda Batiste to determine the extent to
14	A. Don't have an answer for that. I just	14	which formalin would impact your LCMS findings;
15	know this is characteristic of PYMS. LCMS gives	15	true?
16	in this case because we don't have the	16	A. Well, we did it, but it's in reference
17	background, we don't have the degree of	17	one. Remember we're going to use these data
18	problems.	18	together. Because we already have two formalin
19	Q. Just so I understand	19	controls in the what do you call the
20	A. It doesn't always not work either,	20	Exhibit 1.
21	it's a matter of a judgment call.	21	Q. Okay.
22	Q. But you got PYMS testing and results	22	A. So yes, we have controls of formalin.
23	in all but four of the samples you tested in	23	Q. So whatever
24	Exhibit 1, correct? That's on Page 15 and 16.	24	A. Page 92
25	A. Oh, Exhibit 1?	25	Q whatever conclusions might be drawn
	Page 243		Page 245
1	Q. Yes.	1	from the formalin control samples and their
2	A. Well, I know that one thing that's	2	impact on the antioxidants that may have been
3	happened since this work was done was a column	3	present in the mesh apply equally to your
4	had to be changed out.	4	findings for Linda Batiste?
5	Q. What does that mean?	5	A That's as we at
	A. Well, the column eventually goes, and		A. That's correct.
6		6	Q. Now, the control sample that you
6 7	we have to cycle it out. So another column	6 7	
	is this is not the same column that was run	l .	Q. Now, the control sample that you
7		7	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will
7 8	is this is not the same column that was run	7 8	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of
7 8 9	is this is not the same column that was run for the prior samples. So the selectivity is	7 8 9	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct?
7 8 9 10	is this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that	7 8 9 10	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct? A. Okay. What am I on Page 50?
7 8 9 10 11 12 13	is this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that the I'm sure of this, that it's being buried under polypropylene fragments. Q. So are you telling me that the results	7 8 9 10 11 12 13	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct? A. Okay. What am I on Page 50? Q. On Page 50, Table 12. A. Okay. 3422128. Q. You show that Santonox quantitation,
7 8 9 10 11 12 13	is this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that the I'm sure of this, that it's being buried under polypropylene fragments. Q. So are you telling me that the results that you've obtained in Exhibit Number 1 for the	7 8 9 10 11 12 13	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct? A. Okay. What am I on Page 50? Q. On Page 50, Table 12. A. Okay. 3422128. Q. You show that Santonox quantitation, correct?
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7 8 9 10 11 12 13 14 15	is this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that the I'm sure of this, that it's being buried under polypropylene fragments. Q. So are you telling me that the results that you've obtained in Exhibit Number 1 for the PYMS data are different from the results that you obtained for the Linda Batiste sample in	7 8 9 10 11 12 13 14 15	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct? A. Okay. What am I on Page 50? Q. On Page 50, Table 12. A. Okay. 3422128. Q. You show that Santonox quantitation, correct? A. In that table. Q. Why did you choose the 4,430,284
7 8 9 10 11 12 13 14 15 16 17	is this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that the I'm sure of this, that it's being buried under polypropylene fragments. Q. So are you telling me that the results that you've obtained in Exhibit Number 1 for the PYMS data are different from the results that you obtained for the Linda Batiste sample in Exhibit 2?	7 8 9 10 11 12 13 14 15 16	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct? A. Okay. What am I on Page 50? Q. On Page 50, Table 12. A. Okay. 3422128. Q. You show that Santonox quantitation, correct? A. In that table. Q. Why did you choose the 4,430,284 figure as the control against which you compare
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	is this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that the I'm sure of this, that it's being buried under polypropylene fragments. Q. So are you telling me that the results that you've obtained in Exhibit Number 1 for the PYMS data are different from the results that you obtained for the Linda Batiste sample in Exhibit 2? A. It's a different column, so the selectivity is a little bit different. Quantitation of additives is much more difficult than PYMS than it is it's good for detection and confirming the presence of things, it's not	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct? A. Okay. What am I on Page 50? Q. On Page 50, Table 12. A. Okay. 3422128. Q. You show that Santonox quantitation, correct? A. In that table. Q. Why did you choose the 4,430,284 figure as the control against which you compare Santonox? A. It's in the middle. Hang on, let me check this again. Q. I don't see that value in the controls on Page 96. It should be there, shouldn't it?
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	is this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that the I'm sure of this, that it's being buried under polypropylene fragments. Q. So are you telling me that the results that you've obtained in Exhibit Number 1 for the PYMS data are different from the results that you obtained for the Linda Batiste sample in Exhibit 2? A. It's a different column, so the selectivity is a little bit different. Quantitation of additives is much more difficult than PYMS than it is it's good for detection and confirming the presence of things, it's not good for quantitating anything.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct? A. Okay. What am I on Page 50? Q. On Page 50, Table 12. A. Okay. 3422128. Q. You show that Santonox quantitation, correct? A. In that table. Q. Why did you choose the 4,430,284 figure as the control against which you compare Santonox? A. It's in the middle. Hang on, let me check this again. Q. I don't see that value in the controls on Page 96. It should be there, shouldn't it? A. 3422128.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	is this is not the same column that was run for the prior samples. So the selectivity is slightly different. And I'm telling you that the I'm sure of this, that it's being buried under polypropylene fragments. Q. So are you telling me that the results that you've obtained in Exhibit Number 1 for the PYMS data are different from the results that you obtained for the Linda Batiste sample in Exhibit 2? A. It's a different column, so the selectivity is a little bit different. Quantitation of additives is much more difficult than PYMS than it is it's good for detection and confirming the presence of things, it's not	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Now, the control sample that you choose here on Page 50 is 3422128, and that will be, again, from the controls on Page 96 of Exhibit 1, correct? A. Okay. What am I on Page 50? Q. On Page 50, Table 12. A. Okay. 3422128. Q. You show that Santonox quantitation, correct? A. In that table. Q. Why did you choose the 4,430,284 figure as the control against which you compare Santonox? A. It's in the middle. Hang on, let me check this again. Q. I don't see that value in the controls on Page 96. It should be there, shouldn't it?

62 (Pages 242 to 245)

	Page 246		Page 248
1	Q. Do you know why that is?	1	Q. Would it be do you know why this
2	A. That would indicate to me that he	2	new control testing was conducted for Linda
3	reran the control. We extracted it.	3	Batiste?
4	Q. I thought we decided a moment ago they	4	A. Well, the response of the detectors,
5	didn't.	5	the HPLC type, LCMS detectors can change over
6	A. Most of the tests they didn't. I can	6	time, so it would just be good lab practice,
7	check that.	7	since this was run at a different time from the
8	Q. Okay. So what this says is that we	8	other samples, to rule out any change that way.
9	have yet a third value for this	9	Whereas an SEM photograph is an SEM photograph,
10	A. Standard.	10	it wouldn't matter, so there would be no need to
11	Q control	11	rerun those.
12	A. Control.	12	Q. Tell me again what it means to change
13	Q test.	13	the column.
14	Not standard, it's a control?	14	A. Well, when you're doing
15	A. Control.	15	chromatography, columns wear out, and you have
16	Q. So the value here of 4430284, you	16	to periodically change them. The peaks get
17	think is a new test of mesh tested with Carolyn	17	broad, they get narrower, materials start to
18	Lewis?	18	bleed into peaks start to bleed into one
19	A. Correct.	19	another, and it's just time to change the
20	Q. As you sit here today, do you know any	20	column. It's just normal what we call normal
21	other new tests that were conducted for Linda	21	maintenance, like changing the oil in a car.
22	Batiste in order to do on the controls that	22	Q. How do you determine when it's
23	were used to compare the Linda Batiste mesh	23	appropriate to change the column?
24	samples?	24	A. You have standards that you run, and
25	A. Let's check the control in Table 11	25	you look for resolution standards. And when the
	Page 247		Page 249
1		1	
1 2	just to see. All right. Let's go back. 34221228.	1 2	resolution no longer meets the minimum standard, it's time to change it. It's part of the SOP.
3	Q. What page are you on, please?	3	Q. How often do you change the column?
4	A. 92 and 49. It's the number of it's	4	A. When? I don't know how to answer
5	the same standard run for the lauryl	5	that.
6	thiodipropionate, but the number is different	6	Q. Every 2,000 miles?
7	again. So it's certainly right on the same	7	A. It's when it fails, when it fails a
8	range, but it means it's rerun, same thing.	8	test.
9	Q. So the dilauryl has also been rerun?	9	Q. Okay.
10	A. The standard has, yes, along with the	10	A. It's checked every time we run samples
11	actual sample.	11	to see that the minimum resolution is there, or
12	Q. Where are you looking to see that?	12	it's changed.
13	A. Table 11, lot 3422128, Page 49.	13	Q. Before you sat down to give your
14	Q. And that's a value you have two of	14	deposition today, did you realize that the
15	those values from the first one on Page 92, and	15	controls had had additional testing conducted on
16	on Page 92 of Exhibit Number 1 you obtained a	16	them?
17	value of 71,633,460?	17	A. These controls here?
18	A. Mm-hmm.	18	Q. In Exhibit 2 for Linda Batiste.
19	Q. And a duplicate result of 96,522,909,	19	A. No. In all honesty, no.
20	and this is a third value for the same piece of	20	Q. Okay. Fair to understand that a
21	mesh at 82,091,505.	21	doctor would have to give any opinion about the
22	A. Right, between the other two.	22	extent to which any degradation in the mesh that
23	Q. Okay. So do you know of any other new	23	you have found would cause Ms. Batiste any
24	control testing conducted for Linda Batiste?	24	physical harm or other health problems?
25	A. I do not.	25	A. No, I would defer to them for the

63 (Pages 246 to 249)

Page 250 Page 252 1 1 actual physical type damage, it's not -- it's BY MR. THOMAS: 2 2 beyond, out of my field. Q. Do you know whether all of the samples 3 3 MR. THOMAS: I'm going to want copies were tested? 4 4 of everything but the Burkley deposition. The A. No. Some of the samples weren't 5 lab notebooks, the articles, and the SOPs. 5 tested. 6 6 MR. ANDERSON: Just leave them all Q. Do you know why some weren't tested? 7 7 A. There were several that weren't, two there for right now. 8 MR. THOMAS: What's the best way to do 8 or three maybe that weren't tested because they 9 9 were mixtures of multiple products, and we 10 MR. ANDERSON: Good question. The lab 10 didn't want to run those. 11 11 Q. Okay. Is there any way to tell from notebooks obviously can't leave, so we would 12 12 just have to run copies of those for you. All the entries in the lab notebook, to your 13 knowledge, about the reasons why certain ones 13 the other things we can run copies for you. Or 14 weren't tested? 14 we can give them to madame court reporter and 15 have her run some copies. 15 A. Here's one that wasn't run and it 16 16 MR. THOMAS: I don't care just as long wasn't run because -- I'm assuming it wasn't run 17 as I get them. Whatever makes sense. I think 17 because sample received with no formalin. We didn't run it. We didn't know what would happen 18 18 you and I can figure this out. 19 MR. ANDERSON: Okay. 19 to the sample in the absence of preservatives so 20 BY MR. THOMAS: 20 we just didn't run it. 21 21 Q. Doctor, you brought a number of things Q. And who was that? 22 A. We have several here. Cynthia 22 with you to the deposition today including a 23 number of books, a copy of the deposition of Dan 2.3 Simpson, and Alma Sarcia. 24 Burkley. 24 MR. ANDERSON: Garcia. 25 I have here three laboratory 25 A. Garcia. Sorry. JPG240-241, Page 251 Page 253 notebooks. What are these? 1 1 JPG1362-1363. 2 A. These are the laboratory notebooks 2 BY MR. THOMAS: 3 telling the sample preparation and what was done 3 Q. And did you have anything to do with 4 to the samples, and by who, and on what date. 4 the decision not to test those products? 5 Q. What's the purpose of a laboratory 5 A. Well, it would be standard operating 6 б notebook? What are you trying to capture in a procedure that if something comes in in a 7 7 laboratory notebook? non-standard format in a situation as -- well. 8 8 A. We're trying to capture when things any situation, we wouldn't run it without the 9 were done so that we know who did what so we can 9 client's approval. We'd have to go back to them go ask questions of proper people so we have a 10 10 and see if they still wanted to run it, because paper trail for the way the sample was handled. 11 11 otherwise --Q. Is it fair to understand one of the 12 12 Q. Did you, in fact, raise that issue 13 goals of a lab notebook is to provide enough 13 with anybody about whether the sample should be information so that somebody coming behind you 14 14 tested because it did not come in formalin? 15 can understand what you did and recreate it if 15 A. I think the analysts probably got together and discussed it, yeah. necessary? 16 16 17 Q. Did you have any role in the 17 A. Yes. Absolutely. 18 Q. And the lab notebook has a number of 18 decision --19 19 names in here. Are these the people who's A. No, I didn't. That's standard 20 samples were tested, do you know? 20 operating procedure. 21 21 A. You'll have to show me the specifics. Q. Let me finish my question, please. Did you ever any role in the decision 22 (Witness reviewing document.) 22 23 A. Yes, those are the sample --23 not to test the mesh samples that did not come MR. ANDERSON: Hand it back to him. 24 in formalin? 24 25 25 "Yes" answers the question. A. No.

64 (Pages 250 to 253)

	Page 254		Page 256
1	Q. Were you aware before reading the	1	A. Today he is, yes.
2	laboratory notebook today during your deposition	2	Q. Has he been for the last two years?
3	that a decision was made not to test some of the	3	A. Yes.
4	mesh samples because they didn't have formalin?	4	Q. So any testing that would have come in
5	A. Yeah, we've discussed that.	5	Jordi Labs to test polypropylene mesh would have
6	Q. Who have you discussed it with?	6	been overseen by your son Mark? Is that his
7	A. Adi Kulcarni who has been involved in	7	name?
8	this, and my son Mark.	8	A. Yes.
9	Q. What did you discuss about that?	9	Q. To the extent that questions I asked
10	A. Just that we didn't feel it was fit to	10	you before about other mesh that has been
11	run because they were different, they didn't	11	analyzed by Jordi Labs, the person who would
12	match normal composition.	12	know about that is your son Mark?
13		13	A. Yes. Not me.
14	Q. Why? They looked different?A. They were dry, yeah.	14	
15	Q. Okay. Do you know if they'd ever been	15	Q. How long has it been since you've had hands-on responsibility in the lab?
16	in formalin?	16	A. Four, five years now.
17		17	•
18	A. I assume they had, but I have no way	18	Q. And what do you do here at Jordi Labs? A. I'm involved in R&D. And I act as an
19	to know that. They're supposed to send them to us in formalin, so you've got to assume they	19	expert witness. I review jobs as requested. We
20		20	
21	were sent in formalin at some point.	21	try to have three or four or five people review
22	Q. Okay.	22	every job that goes out to look for errors, that
23	A. And it was lost. We don't know when.	23	kind of thing. I'm working in developing new
24	MR. ANDERSON: Don't assume things	24	products.
25	that you don't know. If you know the answer,	25	Q. How much of your time is spent
25	then you say I know the answer.	25	consulting as an expert witness?
	Page 255		Page 257
1	THE WITNESS: I don't know the answer.	1	A. Well, generally it's a sideline, this
2	MR. ANDERSON: If you don't know the	2	case being a little bigger than most that we've
3	answer, please say I don't know the answer,	3	seen.
4	okay?	4	Q. In the last three months, how much of
5	BY MR. THOMAS:	5	your time has been occupied by this case?
6	Q. How many samples did you receive	6	A. Three months, probably 50 percent.
7	without formalin that you didn't test?	7	Q. Okay. What have you done the other 50
8	(Witness reviewing document.)	8	percent of the time?
9	A. Looks like two.	9	A. Well, as I said, I'm reviewing jobs,
10	BY MR. THOMAS:	10	I'm working on developing new products, which
11	Q. And you identified one of them.	11	I've been doing for years.
12	What's the other one? Can you identify that for	12	Q. In the last two years, have you had
13	me, please?	13	any responsibility for supervising the
14	MR. ANDERSON: He said both those	14	activities in the lab?
15	names.	15	A. In the last two years?
17/			(3. 1/
16	A. I said both.	16	Q. Yes.
17	BY MR. THOMAS:	17	A. No.
17 18	BY MR. THOMAS: Q. I'm sorry. Thank you.	17 18	A. No. Q. All right. And you rely on your son
17 18 19	BY MR. THOMAS: Q. I'm sorry. Thank you. Who runs your lab?	17 18 19	A. No. Q. All right. And you rely on your son to make sure that that goes off and the work
17 18 19 20	BY MR. THOMAS: Q. I'm sorry. Thank you. Who runs your lab? A. My son and his business partner.	17 18 19 20	A. No. Q. All right. And you rely on your son to make sure that that goes off and the work gets done as it needs to get done?
17 18 19 20 21	BY MR. THOMAS: Q. I'm sorry. Thank you. Who runs your lab? A. My son and his business partner. Q. What's his business partner's name?	17 18 19 20 21	A. No. Q. All right. And you rely on your son to make sure that that goes off and the work gets done as it needs to get done? A. Right.
17 18 19 20 21 22	BY MR. THOMAS: Q. I'm sorry. Thank you. Who runs your lab? A. My son and his business partner. Q. What's his business partner's name? A. Patrick Burke.	17 18 19 20 21 22	A. No. Q. All right. And you rely on your son to make sure that that goes off and the work gets done as it needs to get done? A. Right. Q. Is Jordi Labs privately held?
17 18 19 20 21 22 23	BY MR. THOMAS: Q. I'm sorry. Thank you. Who runs your lab? A. My son and his business partner. Q. What's his business partner's name? A. Patrick Burke. Q. Is he the person is your son the	17 18 19 20 21 22 23	A. No. Q. All right. And you rely on your son to make sure that that goes off and the work gets done as it needs to get done? A. Right. Q. Is Jordi Labs privately held? A. Yes, it is.
17 18 19 20 21 22	BY MR. THOMAS: Q. I'm sorry. Thank you. Who runs your lab? A. My son and his business partner. Q. What's his business partner's name? A. Patrick Burke.	17 18 19 20 21 22	A. No. Q. All right. And you rely on your son to make sure that that goes off and the work gets done as it needs to get done? A. Right. Q. Is Jordi Labs privately held?

65 (Pages 254 to 257)

	Page 258		Page 260
1	Q. Who are they?	1	Q. Do you specifically know how that
2	A. My son and his business partner.	2	happened?
3	Q. You no longer are an owner of Jordi	3	A. Not exactly, I don't.
4	Labs?	4	Q. Okay. That's fine.
5	A. No. My son. I wanted to get out in	5	And what did you do to assure that
6	time from the ownership situation.	6	Evans Analytical Group and what's the other
7	Q. Okay. And when did that happen?	7	company?
8	A. I don't remember exactly. It's four	8	MR. ANDERSON: They're both Evans.
9	or five years.	9	A. They're both Evans, different
10	Q. How many employees does Jordi Labs	10	divisions.
11	have now?	11	BY MR. THOMAS:
12	A. Again, I don't know exactly. It	12	Q. Sorry. Strike that.
13	changes every day. I'd say 25, 26, around	13	What did you do to assure that the
14	there.	14	Evans Analytical Group was capable of performing
15	Q. Do you know what percentage of the	15	the work that you asked them to do?
16	Jordi Labs work is legal consulting on legal	16	A. We've been working with a gentleman at
17	cases?	17	Chemir, and we've been referring jobs back and
18	A. Well, generally it's a small	18	forth for years at various times, and he is
19	percentage. As I say, right now it's a bigger	19	he's really our contact with Evans. We've had
20	percentage because of the nature of this case,	20	tremendous results for a number of years working
21	but it's an unusual situation.	21	with both ways, he sends a lot of work here,
22	Q. In this stack of documents are a	22	we send some we send a lot of work his way.
23	number of reports from an Evans Analytical	23	Q. So the FTIR strike that.
24	Group.	24	So all of the data done by Evans was
25	A. Right.	25	added to your report without change or input
	Page 259		Page 261
1	Q. Tell me what those are, please.	1	from you?
2	A. The FTIR microscope work was done by	2	A. Yes. Basically you have those
3	Evans in California, and the SEM, SEM-EDX was	3	results. Any changes you can see there. I'm
4	done by Evans Group in Minnesota.	4	sure there were a few verbal changes, but
5	Q. Is that because you don't have the	5	essentially it's the IR spectra, the IR spectra.
6	A. We don't have those instruments.	6	We certainly wouldn't have we wouldn't even
7	Q. How did you happen to choose the Evans	7	have the capability of changing those spectra.
8	Analytical Group to perform this testing?	8	Q. Okay. Has Jordi Labs ever had an
9	A. We've worked with a company called	9	electron microscope?
10	Chemir in the past, they were bought out by	10	A. No.
11	Evans, and they're, I think, about a \$7 billion	11	Q. Has Jordi Labs ever had the capability
12	company, and they're a very well respected lab,	12	to do the FTIR analysis?
13	so we utilize their technique that we don't	13	A. Yes.
14	have.	14	Q. When did you have that?
15	Q. Is it the FTIR data	15	A. Oh, probably well, we've had it
16	A. FTIR microscope.	16	since basically day one of the company at
17	Q. Okay. So for the FTIR and the	17	various units. Classical FTIR. Now we have the
18	scanning electron microscope work, you ship that	18	Diamond ATR system.
19	out?	19	Q. You still have it?
20	A. That's correct.	20	A. Absolutely.
21	Q. And how did you transport the samples?	21	Q. Why do you ship this out to Evans?
22	A. They were sent by our office staff	22	MR. ANDERSON: Micro.
23	following the regulations that we procedures	23	A. Micro.
24	that were set up and described to us to handle	24	BY MR. THOMAS:
25	and to keep chain of custody.	25	Q. I'm sorry. Okay.

66 (Pages 258 to 261)

	Page 262		Page 264
1	Has Jordi ever had the capability to	1	how to conduct the tests that you did?
2	do the kind of work that Evans did on the FTIR?	2	A. That's right.
3	A. No, we have never had an FTIR	3	Q. Diamond Shamrock Corporation, is this
4	microscope system.	4	a standard for polypropylene, or can you tell by
5	Q. Who is Scott Bowman?	5	looking at it?
6	A. He's the gentlemen that transfers jobs	6	A. Let me take a look. I can't read it
7	back and between us and Evans, or he sends us	7	from there.
8	work, we send him work.	8	Q. (Handing).
9	Q. Does he work for Jordi or work for	9	A. Yes, that's the polypropylene standard
10	Evans?	10	spectrum. Isotactic.
11	A. He works for himself.	11	Q. When we talked before, I thought we
12	Q. Pretty good gig.	12	decided you didn't use a standard against which
13	A. It's worked out extremely well for us	13	to compare your results, that you used your own
14	and extremely well for him. We love his	14	training, education, literature.
15	expertise and his ability to get us in touch	15	A. There's no way for me to keep track of
16	with the best people.	16	everything these people are doing out here now.
17	Q. He's not a is he a technical guy?	17	I'm telling you the polystyrene is the one
18	A. Absolutely is.	18	that's used.
19	Q. Does he do any technical work?	19	Q. Do you know the extent to which the
20	A. No, he just basically is	20	people in the lab used that Diamond Shamrock
21	Q. He's a broker?	21	standard for polypropylene in connection with
22	A. He's a broker, a very good one.	22	their work on the opinions in Exhibit 1 or 2?
23	Q. So on these SEM analysis reports here	23	Do you know?
24	that you got apparently from Evans	24	A. No, because these this isn't an SOP
25	A. He may	25	anyway. This is just a bunch of spectra. I'm
	Page 263		
	rage 203		Page 265
1	MR. ANDERSON: Hold on.	1	page 265 not sure why that's even in there, it's not SOP.
1 2	MR. ANDERSON: Hold on. BY MR. THOMAS:	2	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a
	MR. ANDERSON: Hold on.	2 3	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993
2 3 4	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from?	2 3 4	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock
2 3 4 5	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right.	2 3 4 5	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene.
2 3 4 5 6	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right. Q. Is it likely that the numbers that I	2 3 4 5 6	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene. What's the document I just gave you
2 3 4 5 6 7	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right. Q. Is it likely that the numbers that I asked you about in both reports on the SEM	2 3 4 5 6 7	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene. What's the document I just gave you there, do you know? Do you recognize that?
2 3 4 5 6 7 8	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right. Q. Is it likely that the numbers that I asked you about in both reports on the SEM images, likely those were put on there by Evans,	2 3 4 5 6 7 8	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene. What's the document I just gave you there, do you know? Do you recognize that? A. It's another polypropylene spectrum,
2 3 4 5 6 7 8 9	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right. Q. Is it likely that the numbers that I asked you about in both reports on the SEM images, likely those were put on there by Evans, or do you know?	2 3 4 5 6 7 8 9	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene. What's the document I just gave you there, do you know? Do you recognize that? A. It's another polypropylene spectrum, J7904.
2 3 4 5 6 7 8 9	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right. Q. Is it likely that the numbers that I asked you about in both reports on the SEM images, likely those were put on there by Evans, or do you know? A. They would have had to have been put	2 3 4 5 6 7 8 9	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene. What's the document I just gave you there, do you know? Do you recognize that? A. It's another polypropylene spectrum, J7904. Oh, let me see the other one again,
2 3 4 5 6 7 8 9 10	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right. Q. Is it likely that the numbers that I asked you about in both reports on the SEM images, likely those were put on there by Evans, or do you know? A. They would have had to have been put on by Evans because we couldn't have done it.	2 3 4 5 6 7 8 9 10	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene. What's the document I just gave you there, do you know? Do you recognize that? A. It's another polypropylene spectrum, J7904. Oh, let me see the other one again, please.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right. Q. Is it likely that the numbers that I asked you about in both reports on the SEM images, likely those were put on there by Evans, or do you know? A. They would have had to have been put on by Evans because we couldn't have done it. Q. Okay. A. It's their pictures. Q. Do you have these in an electronic format? I'm sure you do. Digital format? A. I'm sure we can get them. Adi, again, would know, handles that kind of thing for me. Q. Did you do all the other testing in-house? A. Yes, we did. Q. The documents that I'm going through	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene. What's the document I just gave you there, do you know? Do you recognize that? A. It's another polypropylene spectrum, J7904. Oh, let me see the other one again, please. Q. (Handing). (Witness reviewing document.) A. These appear to be spectra of the explants done on our instrument which were polypropylene. We saw lots of noise. This is why we chose to go with the FTIR microscope route. We had to look at the total samples, number one. Number two, the samples wouldn't lay flat on our Diamond, and they tended to want to
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. ANDERSON: Hold on. BY MR. THOMAS: Q the numbers appear that I asked you about, you didn't know where they came from? A. Right. Q. Is it likely that the numbers that I asked you about in both reports on the SEM images, likely those were put on there by Evans, or do you know? A. They would have had to have been put on by Evans because we couldn't have done it. Q. Okay. A. It's their pictures. Q. Do you have these in an electronic format? I'm sure you do. Digital format? A. I'm sure we can get them. Adi, again, would know, handles that kind of thing for me. Q. Did you do all the other testing in-house? A. Yes, we did. Q. The documents that I'm going through now are Jordi SOPs, is that correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	not sure why that's even in there, it's not SOP. Q. Okay. Just for the record, it's a multi-page document copyrighted 1980, 1981, 1993 for Sadtler, and it's Diamond Shamrock Polypropylene. What's the document I just gave you there, do you know? Do you recognize that? A. It's another polypropylene spectrum, J7904. Oh, let me see the other one again, please. Q. (Handing). (Witness reviewing document.) A. These appear to be spectra of the explants done on our instrument which were polypropylene. We saw lots of noise. This is why we chose to go with the FTIR microscope route. We had to look at the total samples, number one. Number two, the samples wouldn't lay flat on our Diamond, and they tended to want to bounce around because they were rigid, and so it

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	Page 266		Page 268
1	number one, hone in on the cracked regions.	1	can find out if those are extra copies. If
2	When you run a sample with an instrument like	2	those are extra copies, she can take them with
3	this, you're running can the total sample, so	3	her. If they're not, then we'd like to leave
4	you're diluting the effect on the cracked	4	them here so that we can make copies, or we can
5	regions, you'd be running a combination of	5	have you take them and make copies. I think I
6	cracked and uncracked regions. When we use the	6	need to make sure they're not originals.
7	IR microscope, you can hone in on any specific	7	MR. THOMAS: Here's what I'd like to
8	region of the fiber we want, that's the	8	have, you tell me if I can have it. I'd like to
9	advantage. So we decided to go with that	9	have a hard copy and a digital copy.
10	technique because it offered us for what we	10	MR. ANDERSON: Well, I'd like to have
11	needed for this work, it's a far better	11	a million bucks and retire tomorrow, so if you
12	methodology.	12	can deliver I will.
13	Q. Before I showed you these documents,	13	MR. THOMAS: You can't retire on a
14	were you aware that Jordi Labs had tried to	14	million dollars, I know you.
15	analyze in-house	15	MR. ANDERSON: It will last me a
16	A. Yes, I was.	16	
17		17	couple months. MR. THOMAS: That wouldn't keep you in
18	Q the FTIR spectra for these	18	Red Bull.
19	explants? A. Yes, I was.	19	MR. ANDERSON: If you're getting
20	Q. Okay. And you tried it, and the	20	, ,
21		21	digital well, hopefully they have it in
22	documents you just looked at are the documents	22	digital, then we'll give it to madame court reporter and it will be an exhibit to the depo.
23	that you generated in-house from your results of	23	* *
24	your analysis, correct?	24	If that will still be in digital for you, so
25	A. That's I'm sorry, go ahead, ask the question again. I'm sorry.	25	you need a hard copy. We'll do the best we can. If it's digital
	•	23	
_	Page 267		Page 269
1	Q. I will mark as Exhibit Number 7 the	1	MR. THOMAS: Digital is my first
2	documents you've just been looking at.	2	choice, I'll print my own copy. The hard copy
3	(Whereupon, Jordi Exhibit Number 7,	3	allows me to know I have everything. Not
4	Group of films, was marked for	4	because I'm suggesting you're going to do
5	identification.)	5	anything with it.
6	BY MR. THOMAS:	6	MR. ANDERSON: No, it's easier. I'm a
7	Q. And the first page is the Diamond	7	hard copy guy, too. Why don't we figure that
8	Shamrock standard from Sadtler, S-A-D-T-L-E-R,	8	out after the depo.
9	and then attached to that are FTIR spectra that	9	BY MR. THOMAS:
10	you all ran in-house with your own capability,	10	Q. I'd also like a color copy of your
11	at which point you determined that you weren't	11	studies that you have.
12	generating the specificity of the data you	12	A. You'd like a what, sir?
13	needed to make your analysis so you contracted	13	Q. Color copy so I can capture the
14	it out for microscopic FTIR?	14	highlighting in your studies. Because you
15	A. That's correct.	15	brought with you today a notebook of studies
16	Q. Is that fair?	16	upon which you rely for your opinions in the
17	A. That's fair.	17	case.
18	Q. Mark that as Exhibit Number 7.	18	A. Articles, yes.
19	MR. THOMAS: I won't mark the lab	19	Q. And you have highlighting and writing
20	notebooks.	20	on them, correct?
21	The rest of what I have here are	21	A. Mostly highlighting, yes.
22	miscellaneous SOPs, the Evans reports, and the	22	Q. I want versions of those that capture
22	Evans reports. Do you want the court reporter	23	the highlighting.
23			
23 24 25	to have those, or how do you want to do this? MR. ANDERSON: What we can do is we	24 25	MR. ANDERSON: Absolutely. A. Fair enough.

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Page 270 Page 272 MR. ANDERSON: We need to take a 1 1 Q. And your job as an analytical chemist 2 2 break. Let's take a break. was to do the lab work associated with any 3 3 issues that might arise? (Whereupon, a recess was taken from 4 4 4:39 p.m. to 4:56 p.m.) A. Whatever came up. Whatever projects 5 5 BY MR. THOMAS: they wanted support for. 6 6 Q. Doctor, attached to Exhibit 1 is a Q. All right. And the extent to which 7 7 any of these products may be appropriate for use part of -- oh, right after your primary report, 8 is your CV. I'm just going to ask you some 8 in humans would be something beyond what you 9 9 questions about your career. You can look at were doing in the lab on the bench? 10 the CV if you want to. I imagine you know it 10 A. Yes. 11 Q. Okay. What did you do -- you were 11 pretty well. 12 A. Where is it here? What page? 12 next employed for six months at Waters 13 13 Associates. What were you have doing there; Q. It's after Page 102. I bet you it's 14 14 more of the same analytic chemist group? in the back of that. 15 A. Appendix. Conclusion. 15 A. Basically Waters at that time was, 16 16 MR. ANDERSON: After Page 102? still is a great company, but by my standards, 17 MR. THOMAS: That's where I have it. 17 my personality, I like a company that's personable with their customers. They had a 18 18 It will be in that copy right there. 19 A. All right. That's fine. 19 philosophy at that time that they would work to 20 MR. THOMAS: We've got it here, Ben. 20 solve the customer's separation need and earn 21 21 the sale of the HPLC instrument through A. Okay. BY MR. THOMAS: 22 22 providing the solution of their separations 23 23 problem, and so my job was to develop those Q. All right. Tell me about your education after college, Dr. Jordi. I mean methods. The sales rep would come in and say 24 24 25 after high school. 25 "this guy wants to separate such and such, and Page 271 Page 273 1 A. I went to Northern Illinois University 1 get me a method so we can sell the instrument." 2 in DeKalb, Illinois, worked on my bachelor's 2 Q. Okay. 3 degree in chemistry, graduated in the summer of 3 A. At that time liquid chromatography was 4 1967. 4 nowhere near as advanced as it is now, so if a 5 Was offered a graduate position there, 5 guy wanted to separate something, likely there 6 б an NIH fellowship, so I stayed there and worked was no published methods available many times, 7 7 on my doctorate degree. I finished that in so then we would get involved. 8 8 1973, and actually officially graduated in Q. So were your years -- or your time at 9 January of '74, but I'd already left and was 9 Waters dealing primarily with liquid 10 already in the US Army at Walter Reed by that 10 chromatography? A. Yes, or columns. 11 point. 11 Q. You worked at Walter Reed for how many 12 12 O. Or columns. Does that include your entire time at 13 years? 13 14 A. A little over three years. 14 Waters up until February, 1980? 15 Q. What did you do at Walter Reed? 15 A. Yes. Developed amino acid, worked on A. It was a lab tech chemist position. I 16 developing an amino acid analyzer, first 16 worked with, as I mentioned, the biodegradable 17 generation amino acid analyzer. And then they 17 18 implants, polylactic and glycolic acid 18 sent me places to install amino acid analyzers, copolymers. We had an another project for 19 19 like they sent me to Germany, they sent me to 20 purification of eugenol, which is used by 20 Chicago. 21 21 dentists. I worked on developing methods of Q. Continuing in the analytical chemistry 22 purifying eugenol. 22 area? 23 Q. You were employed at this time as an 23 A. Yeah, it was amino acid analysis at 24 analytical chemist? 24 this point, that was the specialty at that point 25 25 A. Basically. in time. It always kept changing depending on

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Page 274 Page 276 1 Q. How would you describe the business of 1 the needs of the company, of course. 2 2 Jordi Labs today? Q. Then you went for a short time to LC 3 3 Laboratories? A. We're an analytical testing lab, 4 4 A. I'm looking at the order of these material science, some expert witness testimony, 5 5 it's not the major thrust by any stretch, pages here. 6 6 Q. You go back to front, I think. product development. Because the other side of 7 A. There's Army. The pages aren't 7 the business that I developed during my time is 8 listed. 8 several dozen products, fluorinated gel that I 9 9 MR. ANDERSON: Is this it here? patented that's selling. 10 A. Where are we here? 10 Q. What does a fluorinated gel do? 11 A. Well, in chromatography, as you run 11 BY MR. THOMAS: 12 12 fast -- liquid chromatography, or any Q. Hopefully February, 1980 to September, 13 13 1980, it looks like you were employed by LC chromatography, as you run faster you'll tend to Laboratories as a senior chemist? 14 get less efficient plates. Plates is a 14 15 A. That's right. 15 narrowness of the peaks coming off, and the 16 16 Q. You managed the complete polymer GPC narrower they are the better, the more things 17 17 separated the narrower they are. program? 18 So with the fluorinated gel, solvents, 18 A. Right. I was working at the time with 19 a Waters 150C, which is a high temperature GPC 19 it's like Teflon surface chemistry, solvents 20 system running high temperature samples, among 20 tend not to wet it. Since solvents don't wet 21 21 other things, and I was responsible for surface, they don't create drag, and that's what 22 22 broadens the peaks. And so now I can run maintaining that instrument. 23 23 And we also were a contract lab, so we something at 10 mils a minute instead of one mil 24 got all kinds of projects. Whatever the 24 a minute, I can run at one-tenth the time on 25 customers sent in they wanted us to do, we did, 25 that kind of column. Page 275 Page 277 1 iust like we have here now. 1 I developed a polyamide type column, 2 Q. Same kind of internal analytical work? 2 we call it Extreme. It's a column that runs 3 A. Yes. 3 things in water, polar solvents, so today our 4 Q. Okay. 4 polyamides, nylons, proteins, can be run on the 5 5 A. It might be prep, it might be Extreme material. 6 б developing analytical method, it might be I have a standard line of DVD resins 7 7 polymer formulation, whatever, whatever it was. that I've developed. Those are selling well. 8 8 Q. And then from October of 1980 until And basically there's a whole product 9 July, 2008 you ran your own show? 9 line. There's SFE product, solid face 10 A. That's right. Remember I told you 10 extraction cartridges. 11 four or five years, that's where it is. 2008 we 11 Q. Is it fair to describe your business 12 as a lab that offers analytical chemistry 12 turned it over to Mark. 13 Q. Has the business of Jordi Labs largely 13 services to those who might need it? 14 been the same over the time frame it's operated? 14 A. Yes. 15 A. Yes. But we're continuing to add 15 Q. And whatever other products you all 16 instrumentation. So some of the instruments we 16 might develop on your own? 17 don't have now, if you come back in a few years, A. The products we developed are no 17 18 lord willing, we will have. Like we're thinking 18 like -- I would say we probably have a million 19 19 dollar column inventory here, if we had to go about an FTIR microscope system, we're thinking 20 about an SEM system. We just invested in a QTOF 20 out and buy them all, but we save a good portion 21 21 GC system which should be in within the next few of that money by making them ourselves. And as 22 a side bonus, we sell them on the side and make 22 months to match the LCMS QTOF system, which 23 gives you more accurate mass and better ability 23 money from the sale of them, too, as products. to get more accurate mass and more accurate 24 That was my business model. 24 25 25 identification of unknowns. And when I successfully developed

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	Page 278		Page 280
1	methods for clients, then they would say they	1	A. The same type of thing, molecular
2	might say "okay, now you run \$100,000 worth or	2	weight, additives.
3	\$200,000 worth of samples, I want to take that	3	Q. How long ago did you do the hip
4	in-house, sell me the column, turn-key method."	4	implant work?
5	They've already seen my methods here, they've	5	A. The same thing.
6	seen the results, they just take the column and	6	Q. 20 years ago?
7	start running. But now I don't use the total	7	A. 20 years ago-ish.
8	business, I have a column customer instead of a	8	Q. Have you done anything in the last ten
9	sample customer.	9	years in hip implants?
10	Q. So when you talk about the methods,	10	A. No, I haven't seen it recently.
11	you're talking about methods of analytical	11	Q. Do you remember who you worked with on
12	chemistry that you come up with for your	12	hip implants?
13	customers?	13	A. No.
14	A. Yes.	14	Q. Did you give any depositions in hip
15	Q. Prior to your deposition today, have	15	implant litigation?
16	you ever testified or consulted in a medical	16	A. I don't think so.
17	device case?	17	Q. Do you know whether Jordi Labs works
18	A. I have testified. I don't think, I	18	on any current hip implant litigation?
19	don't recall well, I have been involved with	19	A. No. No, I shouldn't say I have to
20	polypropylene implants, artificial hips,	20	say I don't know because I really don't know
21	artificial knees, polyethylene, I believe. I've	21	what the current workflow is. I don't talk to
22	been involved with contact lenses. I don't	22	the customers anymore directly. I used to know
23	I've been involved in the legal cases, many	23	that intimately, but I don't now.
24	times they don't go to court, they settle, so	24	Q. Contact lenses, have you done any work
25	you say testify, testifying has been less, of	25	on contact lenses in the last 15 years?
	Page 279		Page 281
1	course, than the work for because people will	1	A. I couldn't name the customers. I
2	come to me and not even tell me it's a legal	2	suspect we have because we've worked on
3	case, then they'll see the results and then tell	3	methacrylate type gels, and hematype gels which
4	me they want to do more and now they'll tell me		
	me they want to do more than now they is tell into	4	are used in that kind of product.
5	it's a legal case.	4 5	
			are used in that kind of product.
5	it's a legal case. Q. What did you do in connection with knee implants?	5	are used in that kind of product. Q. In a litigation context?
5 6	it's a legal case. Q. What did you do in connection with knee implants? A. I just ran GPC, additives.	5 6	are used in that kind of product. Q. In a litigation context? A. No, just analysis. Q. For the knees, hips, and contact lenses that you just identified, do you recall
5 6 7 8 9	it's a legal case. Q. What did you do in connection with knee implants? A. I just ran GPC, additives. Q. Analytical testing?	5 6 7 8 9	are used in that kind of product. Q. In a litigation context? A. No, just analysis. Q. For the knees, hips, and contact lenses that you just identified, do you recall giving any deposition testimony in any of those
5 6 7 8 9 10	it's a legal case. Q. What did you do in connection with knee implants? A. I just ran GPC, additives. Q. Analytical testing? A. Just to see if the polymer was	5 6 7 8 9	are used in that kind of product. Q. In a litigation context? A. No, just analysis. Q. For the knees, hips, and contact lenses that you just identified, do you recall giving any deposition testimony in any of those cases?
5 6 7 8 9 10 11	it's a legal case. Q. What did you do in connection with knee implants? A. I just ran GPC, additives. Q. Analytical testing? A. Just to see if the polymer was degraded over periods of time, if the additives	5 6 7 8 9 10 11	are used in that kind of product. Q. In a litigation context? A. No, just analysis. Q. For the knees, hips, and contact lenses that you just identified, do you recall giving any deposition testimony in any of those cases? A. No.
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5 6 7 8 9 10 11 12 13	it's a legal case. Q. What did you do in connection with knee implants? A. I just ran GPC, additives. Q. Analytical testing? A. Just to see if the polymer was degraded over periods of time, if the additives were still there, just like we're doing now. Q. Did you give any deposition testimony	5 6 7 8 9 10 11 12	are used in that kind of product. Q. In a litigation context? A. No, just analysis. Q. For the knees, hips, and contact lenses that you just identified, do you recall giving any deposition testimony in any of those cases? A. No. Q. Have you ever testified as an expert in a medical device case before today?
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it's a legal case. Q. What did you do in connection with knee implants? A. I just ran GPC, additives. Q. Analytical testing? A. Just to see if the polymer was degraded over periods of time, if the additives were still there, just like we're doing now. Q. Did you give any deposition testimony in any cases involving knee implants? A. It's been 20 years ago. I don't recall. I remember running the work, but I don't remember what how deep into it we got. Q. Did you work for the Plaintiff or the Defendant? A. I worked for the manufacturer, whether Q. Do you remember who that was?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	are used in that kind of product. Q. In a litigation context? A. No, just analysis. Q. For the knees, hips, and contact lenses that you just identified, do you recall giving any deposition testimony in any of those cases? A. No. Q. Have you ever testified as an expert in a medical device case before today? A. I don't believe so. Q. Have you ever done any work for the FDA? A. No. Q. Ever done any work for Johnson & Johnson? A. I think we probably have, because we've worked for almost all the major corporations over the years.

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	Page 282		Page 284		
1	A. I have a recollection, but I couldn't	1	Q for this work?		
2	even tell you what we did.	2	A. What's Greg's last name? I can look		
3			it up.		
4	as Ethicon?		MR. ANDERSON: Elsdon.		
5	A. Yes.	5	A. Elsdon.		
6	Q. Do you have any recollection of ever	6	BY MR. THOMAS:		
7	working with Ethicon?	7	Q. And what kind of file materials would		
8	A. The name sure sounds familiar.	8	the company typically keep that would govern the		
9	Q. Do you know the business of Ethicon?	9	relationship that it has with a customer, an		
10	A. Well, I do, I mean I know one part of	10	engagement or purchase order or a contract of		
11	it at least now, these meshes. I don't know, I	11	some sort outlining the work you're going to do?		
12	don't know what else they might be involved in.	12	A. There has to be some kind of		
13	Q. Do you know any business interests	13	paperwork, otherwise we wouldn't begin work.		
14	that Ethicon has beyond the mesh that's involved	14	Q. Anything else?		
15	in the litigation about which you're testifying	15	A. Not very formal, other than that.		
16	today?	16	Q. On the invoices we talked about		
17	A. Other than the mesh?	17	earlier that I marked as an exhibit, there were		
18	Q. Right.	18	a number of surcharges for rush work. Are you		
19	A. No.	19	familiar with those?		
20	Q. And the only reason you know about the	20	A. Yes.		
21	mesh and its relationship to Ethicon is because	21	Q. What happened? Why were the		
22	you're involved in this case, is that fair?	22	surcharges made?		
23	A. That's right.	23	A. Well, like in the Batiste case, the		
24	Q. We talked earlier about work that	24	sample was explanted recently, and we had to be		
25	Jordi Labs may be doing in litigation involving	25	ready for the deposition today, so in order to		
	Page 283		Page 285		
1	Bard. Do you know whether Jordi Labs is doing	1	do that it had to be done on a rush basis or it		
2	work involving the meshes of any other	2	wouldn't be ready. Normal turnaround is ten		
3	manufacturer?	3	days.		
4	A. I don't have any idea.	4	Q. Do you have a pricing policy that		
5	Q. Do you have an engagement letter with	5	determines the extent to which you markup work		
6	the Plaintiffs in this case?	6	for surcharges?		
7	A. No.	7	A. Yeah, they do. It's maybe double. I		
8	Q. Do you know whether Jordi Labs has an	8	don't again, I don't control that. But I'm		
9	engagement letter with the Plaintiffs in the	9	familiar with it.		
10	case?	10	Q. For example, on invoice 7881, there's		
11	A. Well, we have we send out	11	a surcharge for rush analytical surfaces of		
12	quotations, and those have to be signed.	12	\$35,000.		
13	Q. Okay.	13	Would that be a charge in addition to		
14	A. Somehow.	14	what it ordinarily costs?		
15	Q. For work that's been done in this	15	A. Yes.		
16	case, you should have on your file a contract or	16	Q. And again on 7883, 9/11/2013, there's		
17	agreement?	17	another surcharge for \$67,813?		
18	A. That would be the way the work is	18	A. Yes.		
19	handled is it goes through a project manager,	19	We're basically set up		
20	and the project manager would have that quote.	20	MR. ANDERSON: There's no question.		
21	He generates the quotes, and then it's approved	21	THE WITNESS: Sorry.		
22	by Mark and others.	22	MR. ANDERSON: No question pending.		
23	Q. Do you know who the project manager	23	MR. THOMAS: I'm finished. Thank you.		
24	is A. Greg.	24 25	MR. ANDERSON: All right. I need to take a break, take a few minutes and sit and		
25		/ h			

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	Page 286		Page 288		
1	talk, and we'll be back on here as soon as we	1	Jordi Labs, and they brought results back to		
2	2 can.		you, and you interpreted those results?		
3	(Whereupon, a recess was taken from		A. That's right.		
4			Q. Is that also standard in your		
5			industry?		
6	BY MR. ANDERSON:	6	A. Absolutely.		
7	Q. Dr. Jordi, I'm just going to ask you a	7	Q. In talking about your opinions		
	few questions. I know it's been a long day, but	8	regarding the degradation of the meshes from		
	I just have a few follow-up questions to some of	9	Ms. Batiste, Ms. Lewis, and the other women		
	the things Mr. Thomas asked you. Okay?	10	whose explant samples you reviewed today, do you		
11	A. Okay.	11	have an opinion as to whether or not those		
12	Q. Doctor, all of the testing that we've	12	meshes would degrade even if there were		
	been discussing all day long that was performed	13	antioxidants present in the polypropylene?		
	by Jordi Labs, are all those tests industry	14	MR. THOMAS: Object to the form of the		
15	standard?	15	question.		
16	A. Yes. Routine.	16	A. It's possible that they could if the		
17	Q. In performing these tests, the ones	17	amount of peroxide, superoxide, other oxidants,		
	that were done at Jordi Labs, were standard	18	the irritation, the inflammation was great		
	operating procedures here at Jordi Labs	19	enough in a given patient.		
	followed?	20	BY MR. ANDERSON:		
21	A. Yes.	21	Q. You said "possible," so we have to		
22	Q. Were lab notebooks carefully collected	22	correct that.		
23	and each step written down by	23	Do you have an opinion to a reasonable		
24	A. Yes.	24	degree of medical certainty as to whether or not		
25	Q. Let me finish.	25	the meshes in Ms. Batiste, Ms. Lewis, and others		
	Page 287		Page 289		
1	by Jordi Labs?	1	could still degrade showing the cracking on SEM		
2	A. Yes.	2	and showing SEM-EDX analysis of the particles to		
3	Q. And was all of the testing that we've	3	be polypropylene even if there was antioxidants		
4	described today done at your direction?	4	present in the mesh?		
5	A. Yes, I requested these tests.	5	MR. THOMAS: Object to the form of the		
6	Q. Is it standard or non-standard in your	6	question.		
7	industry for someone to assign work or to send	7	MR. ESTEE: Object to form.		
8	work of this nature, this type of testing, to	8	A. It's certainly the antioxidants can		
9	someone else to perform the testing?	9	be overcome if you throw enough oxidant at the		
10	A. It's standard procedure because	10	polymer.		
	nobody, almost nobody has enough, except the	11	BY MR. ANDERSON:		
12	giants, has enough money to have all the	12	Q. Is the sole basis for stating that		
	instruments.	13	antioxidants can leach from polypropylene just		
14	Q. So when Mr. Thomas was questioning you	14	your work done in this case, or are there other		
15	about some of the jobs you sent to Evans, and	15	bases for that opinion?		
	you said sometimes Evans sends jobs to you, is	16	MR. THOMAS: Object to the form of the		
	that standard in your industry?	17	question.		
18	A. Absolutely.	18	A. Certainly additives bloom at varying		
19	Q. Therefore, was it standard for you to	19	rates depending on their compatibility with the		
20	send some of the FTIR microscopy and other tests	20	polymer system they're put in. So Santonox R		
	out to Evans to have them send you the results?	21	can bloom, most any additive can bloom at some		
22	A. Yes.	22	rate, and the less compatible it is with the		
1 2 2	Q. In preparing your report in this case	23	polymer the faster it will bloom, and hence the		
23					
24	and providing your opinions, is it fair to say that you assigned these projects to folks at	24 25	faster it will be lost. So polymers can lose their antioxidants even if they're stabilized		

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	Page 290		Page 292		
1	initially. In fact, they all do at some rate.	1	questioning?		
2	BY MR. ANDERSON:	2	A. Mm-hmm.		
3	Q. And is that knowledge that you just	3	Q. Yes?		
4	expressed based only upon the studies that you	4	A. Yes.		
5	did here, or is that something that you brought		Q. There was some question by Mr. Thomas		
6	with you before this litigation?	5 6	as to whether or not you should have used sodium		
7	MR. THOMAS: Object to the form of the	7	hypochlorite in order to clean the materials.		
8	question.	8	Do you remember that part of the		
9	A. No, the over 30 years of experience	9	questioning?		
10	and articles I've read, books I've read, other	10	A. Yes.		
11	samples I've analyzed, it can be they can	11	MR. THOMAS: Object to the form of the		
12	lose their antioxidants, as well as we showed it	12	question.		
13	in the study. But that certainly isn't the only	13	MR. ANDERSON: I'm trying to redirect		
14	reason I believe they're lost.	14	the witness back to that area of the		
15	BY MR. ANDERSON:	15	questioning.		
16	Q. Right at the end of some of the	16	BY MR. ANDERSON:		
17	questioning there was some Mr. Thomas asked	17	Q. By not applying sodium hypochlorite to		
18	you some questions about some rush charges on	18	the fibers in order to remove some of the		
19	the bills.	19	proteins, would that change any of your opinions		
20	Do you remember those? Do you	20	with regard to whether or not the meshes in		
21	remember those questions?	21	Ms. Lewis, Ms. Batiste, and the other women		
22	A. Yes, sir.	22	whose explanted meshes you looked at degraded on		
23	Q. Is it standard in your industry if	23	SEM analysis?		
24	someone asks you to do a quick turnaround on	24	A. No. The fact is that you could		
25	testing that you charge a rush charge?	25	clearly see the degradation, it had no bearing		
	Page 291		Page 293		
1	A. Absolutely is.	1	whatsoever.		
2	Q. So that wasn't something just special	2	Q. What change, if any, would applying		
3	to me, that's something your company does all	3	sodium hypochlorite have to any of the test		
4	the time?	4	results that you obtained for Ms. Lewis,		
5	A. We yes. Absolutely.	5	Ms. Batiste, and the other women?		
6	Q. Do other companies in your industry do	6	A. It would have removed the protein from		
7	the same thing?	7	the surface of the mesh so that the infrared		
8	A. Absolutely.	8	spectrum would the protein bands in the		
9	Q. Does your dry cleaners do it, too?	9	infrared spectrum would have gone away.		
10	Withdraw the question.	10	Q. Whether or not those bands are present		
11	And why is it that your company would	11	or not present, can you still see other evidence		
12	charge a rush fee?	12	of oxidation on those bands?		
13	A. We have to turn away other work, we	13	A. We still saw the 1760 band and the		
14	have to put other projects on hold, potentially	14	1740 shoulder in spite of that. So they're both		
15	if we get enough of this type of thing, angering	15	still there, both of which indicate oxidation.		
16	some clients. So it's a difficult management	16	Q. You were shown by Mr. Thomas Jordi		
17	decision on how to handle it.	17	Exhibit 3, that was this Renaud de Tayrac and		
18	Q. Does it put an increase on your	18	Letouzey article.		
19	workload for your employees?	19	Do you recall that?		
20	A. Absolutely.	20	A. Yes, I do.		
21	Q. Let me take you back to a part of your	21	Q. Were the meshes that were		
22	testimony regarding cleaning the material or,	22	A. I got it.		
	1 (1 11)				
23	let's call it, preparing the fibers prior to	23	Q. Were the meshes that were explanted		
	let's call it, preparing the fibers prior to certain testing being done at Jordi Labs. Do you remember that part of your	23 24 25	Q. Were the meshes that were explanted and analyzed in that study coming from women? A. No, it says in Figure 1 they were		

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Page 294 Page 296 1 1 coming from Wistar rats. There's no proof there by any chemical testing. 2 2 Q. From rats, is that what you said? Q. Do you recall during part of your --3 A. Yes. Wistar rats. 3 during part of the questioning by Mr. Thomas, he 4 4 Q. And when animal studies are used in a was asking you whether or not you or someone at 5 preclinical model, do they typically use healthy 5 Jordi Labs performed any analysis on hydrogen 6 6 peroxide or any other products of inflammation rats? 7 7 that may have occurred in the women's tissue 8 Q. Was the explanted tissue coming from 8 before these meshes were explanted? Do you 9 9 these women coming from healthy tissue? remember that part of your testimony? 10 MR. THOMAS: Object to the form of the 10 A. I do. 11 11 auestion. Q. Are you aware of any test out there 12 12 that would allow you to look at the products of A. From here, from this figure? BY MR. ANDERSON: 13 13 inflammation in and around mesh fibers that have 14 been explanted and put into formalin and shipped 14 Q. From the women whose explanted meshes 15 you looked at. I'll withdraw -- that's okay, 15 to you for analysis? 16 A. Absolutely not, because it's been 16 I'll withdraw the question. 17 washed away. 17 He used D -- well, these authors used 18 18 DMSO as well as ultrasonic treatment in order to Q. Would it matter to your opinions 19 remove what they claim to be just the proteins 19 regarding the degradation of these meshes in 20 from the fibers. 20 this case whether or not hydrogen peroxide was 21 21 Do you recall that? present in the body at that time? 22 22 A. I do. A. No, it would not, because the damage 2.3 23 was observed in SEM and other techniques, like Q. Do you believe that's a scientifically 24 valid method in which to determine what is 24 25 flaking off of the meshes? 25 Q. Do you, to a reasonable degree of Page 295 Page 297 1 A. I do not. medical -- to a reasonable degree of medical 2 2 certainty --Q. And why is that? A. If you use sonication you're using a 3 3 MR. THOMAS: Scientific certainty. 4 battering ram to knock the cracked material off, 4 BY MR. ANDERSON: 5 and so if you knock the material off you're 5 Q. What did I say? Medical? It's been a 6 б removing the very thing that you want to look long day. 7 7 at. They did not -- now, if they had run Doctor, do you have an opinion to a 8 8 infrared or some other technique to look at the reasonable degree of scientific certainty as to 9 structure of the material coming off chemically, 9 whether or not you need to know whether hydrogen 10 it would have been helpful, but none of that was 10 peroxide, superoxides, or any other mediators or 11 done. So it was just blasted clean, and say it 11 inflammatory products that would have been 12 produced in the body were present on the meshes 12 never was polypropylene, but we know it was 13 polypropylene because we looked at it in our 13 by the time you analyzed them in order to 14 particles, and we saw that it was polypropylene. 14 determine whether or not these meshes degraded? 15 Of course it did have some protein in it, but it 15 A. I don't see why we'd need to determine was mostly polypropylene. 16 16 that. 17 Q. So do you find this article to be 17 Q. And why is that? 18 scientifically reliable with regard to whether 18 A. It wouldn't matter. We see the 19 19 or not TVT mesh degrades in women? Do you find degradation, the oxidation has already occurred, 20 this article to be scientifically valid with 20 we don't need to say hydrogen peroxide or 21 21 regard to whether or not the TVT meshes degrade hydroxide radicals at this point, we need to see the chemical damage that's been done to the 22 in women? 22 23 A. I do not. I think -- I'm surprised it 23 material. It either has or has not occurred. 24 was published without some requirement to do 24 Q. Do you recall some questioning by 25 25 structural analysis to prove their claim. Mr. Thomas where you were looking at the FTIR

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	Page 298		Page 300
1	_	1	
1 2	microscopy, and there was a picture of one of the shards of polypropylene that had come off	1 2	Q. How much oxidation was required for Ms. Lewis, Ms. Batiste, and these other 21
3	one of the meshes?	3	women?
4			
5			A. Enough to cause the flaking that was observed.
6	Q. Do you recall that? Don't cut me off if you can.	5 6	MR. THOMAS: Object to form of the
7	Do you recall that?	7	question. Move to strike.
8	A. Yes.	8	MR. ESTEE: Object to form.
9	Q. Do you recall that he asked you how	9	BY MR. ANDERSON:
10	many of these particles came off of the fibers?	10	Q. How much oxidation was required for
11	Do you remember that?	11	the mesh samples for Linda Batiste, Carolyn
12	A. Yes.	12	Lewis, and all the other women whose meshes you
13	Q. Did you feel the need to count each	13	observed in order to flake?
14	and every particle that came off of those fibers	14	MR. THOMAS: Object to the form of the
15	in order to allow you to make an opinion as to	15	question.
16	whether or not those FTIR microscopy analyses	16	MR. ESTEE: Form.
17	showed that the shards contained polypropylene?	17	A. That's an impossible question for me
18	A. I saw no need, because you can look at	18	to answer. I know that there was enough because
19	the cracked region, and if it came off in bits	19	it did flake and it was observed in the SEM.
20	and pieces, each piece would be the same. It	20	BY MR. ANDERSON:
21	all looks identical.	21	Q. If polypropylene fibers flake in the
22	Q. And just give us an estimate of how	22	manner in which those that you observed in this
23	many of these particles were falling off just	23	testing flaked and peeled off, would that allow
24	one of these small pieces of fibers; are we	24	this mesh to function for its intended purpose?
25	talking tens, twenties, dozens?	25	MR. THOMAS: Object to form of the
	Page 299		Page 301
1	A. I have no idea.	1	question.
2	Q. It's that many?	2	MR. ESTEE: Object to form.
3	MR. THOMAS: Object to form.	3	A. I would think it would cause
4	A. In some cases, like this case, this	4	irritation in the body, so I would think not.
5	article	5	That is a question primarily for the medical
6	BY MR. ANDERSON:	6	doctors to answer as far as the damage it might
7	Q. No, we're going to focus on in this	7	or might not do. But it certainly can't be good
8	case.	8	to be putting knife edges in tissue.
9	A. Okay.	9	BY MR. ANDERSON:
10	Q. The amount of material. Let's focus	10	Q. Is it your understanding that these
11	on that.	11	are supposed to be permanently implanted in a
12	In the photographs that were done by	12	woman's pelvic tissues?
13	Evans on the FTIR microscopy when they showed	13	A. Yes.
14	the various pieces, did you need to test 10, 20,	14	Q. Given the amount of degradation that
15	30 of those pieces to confirm the results that	15	you've seen in your testing, do you believe that
16	you had on your FTIR microscopy?	16	it would perform its intended purpose of being
17	MR. THOMAS: Object to the form of the	17	permanently implanted in these women's bodies
18	question.	18	without causing some problems with the polymer
19	A. No. I mean they're all the same.	19	structures?
20	BY MR. ANDERSON:	20	MR. THOMAS: Object to the form of the
21	Q. Do you recall being asked a question	21	question.
22 23	as to how much oxidation is required to cause	22 23	A. Absolutely not. BY MR. ANDERSON:
24	the polypropylene fibers to begin to flake? Do you recall that part of your questioning?	24	Q. Explain what you mean by that.
25	A. Yes.	25	A. Well, these shards come off, they're
20	11. 100.	ريا	11. TO CIT, LICON SHARAS COINC OIT, LICY IC

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Page 302 Page 304 1 going to cause inflammation, and it's going to 1 to whether or not you found anything in the 2 2 be a problem. FTIR, evidence of oxidation at band 1730 to 3 MR. THOMAS: Move to strike. 3 1680. 4 4 BY MR. ANDERSON: Do you recall that? 5 5 Q. Had these meshes continued to be in A. Yes. 6 6 these women's bodies, would you -- strike that. Q. Does it matter to you whether or not 7 7 Is degradation of polymer, like you've you can find evidence of oxidation in the FTIR 8 seen in this testing, progressive? 8 at 1730 to 1680 in order to hold the opinion 9 9 MR. THOMAS: Object to form of the that this mesh degraded in this woman's body? 10 10 A. Not really, because the fact is it did question. 11 degrade and we saw it in the SEM. That's just 11 A. Yes. It definitely is. It starts on 12 the surface and apparently works its way in, as 12 simply a fact. 13 Q. Is all of the testing that was done 13 we've seen by SEM-EDX presence of oxygen in the 14 14 second underlying layer. for Carolyn Lewis and Linda Batiste contained in 15 BY MR. ANDERSON: 15 the reports that you've provided? 16 16 A. Was all of the testing? Q. So do you have an opinion to a 17 17 reasonable degree of scientific certainty as to Q. Is all of the testing that was done at 18 whether or not the longer these mesh fibers are 18 your direction provided in the reports that 19 in the body the more degradation will occur? Do 19 you've given today for both Linda Batiste and 20 you have an opinion on that? 20 Carolyn Lewis? 21 21 A. I think the data shows that it's going A. Well, with the possible exception of 22 22 to degrade like the layers of an onion, layer the --23 23 after layer. Q. Let me see if I can withdraw that. 24 Q. You were asked some questions about --24 Is all the testing that forms the 25 from Mr. Thomas as to whether or not you used a 25 basis of your opinions that the mesh degraded in Page 305 Page 303 1 standard over here for polypropylene, for FTIR, 1 Linda Batiste and Carolyn Lewis available in the 2 or a standard over here. Do you remember that 2 reports that you've provided today? 3 part of your questioning? 3 4 A. Right. 4 MR. THOMAS: Object to the form of the 5 Q. Do you need an FTIR for polypropylene 5 question. б -- sorry. Strike that. б BY MR. ANDERSON: Do you need an FTIR standard for 7 7 Q. In other words, if you wanted to speak 8 8 polypropylene in order to determine whether or to the results for all of the testing that was 9 not the polypropylene in these meshes oxidized 9 done showing degradation as you've described and degraded? 10 previously here for the jury for Carolyn Lewis 10 11 A. Absolutely not. 11 and Linda Batiste, you'd be able to point us to Q. Please explain that. 12 each one of those testing as Mr. Thomas went 12 13 A. Because we have -- the carbonyl is 13 through with you today, correct? 14 going to show up at 1740, 1730, 17 whatever, 15, 14 MR. THOMAS: Object to form. 15 or 1700 depending on the form, or a mix of all 15 MR. ESTEE: Form. of those, and that's going to be there in a 16 MR. ANDERSON: Form. 16 17 polypropylene. So if the carbonyl shows up, A. That's correct. 17 18 it's going to be separate from the bands of the 18 BY MR. ANDERSON: polypropylene. Polypropylene doesn't have any 19 19 Q. Based on your knowledge, training, 20 bands there. 20 background, experience, your work history with 21 21 Q. Do you recall, if you could just turn polymers as you described it here today, your to Pages 67 and 69 of your report, you were 22 22 work as a biochemist and a polymer chemist, and 23 looking at some FTIR micro with Mr. Thomas? 23 all of the materials that you reviewed in this 24 A. Yes. 24 case, including the testing that was done at 25 your direction, do you have an opinion to a 25 Q. And you were asked some questions as

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	Page 306		Page 308
1	reasonable degree of scientific certainty as to	1	MR. ESTEE: No. We will reserve any
2	whether or not the polypropylene mesh, Prolene	2	questions until the time of trial.
3	mesh TVT implanted in Carolyn Lewis, degraded	3	MR. THOMAS: Thank you.
4	while in her body?	4	(Whereupon, the deposition was
5		5	
6	MR. THOMAS: Object to the form of the	6	concluded at 6:11 p.m.)
7	question.	7	
	MR. ESTEE: Object to form.		
8	BY MR. ANDERSON:	8	
9	Q. Do you have an opinion?	9	
10	A. I absolutely do.	10	
11	Q. What is that opinion?	11	
12	MR. THOMAS: Objection to form.	12	
13	MR. ESTEE: Form.	13	
14	A. It's obvious, you can see the	14	
15	cracking.	15	
16	BY MR. ANDERSON:	16	
17	Q. And do you have an opinion to a	17	
18	reasonable degree of scientific certainty based	18	
19	upon your knowledge, training, background,	19	
20	education, all of your work history for greater	20	
21	than 30 years, 40 years, your work here at Jordi	21	
22	Labs, as well as all of the materials that	22	
23	you've reviewed in this case, including the	23	
24	testing that was done for the explant sample for	24	
25	Linda Batiste, as to whether or not the mesh in	25	
	Page 307		Page 309
1	Linda Batiste degraded in her body?	1	COMMONWEALTH OF MASSACHUSETTS)
2	MR. THOMAS: Objection.	2	SUFFOLK, SS.)
3	MR. ESTEE: Form.	3	I, MAUREEN O'CONNOR POLLARD, RPR, CLR,
4	A. It did degrade. I saw the damage.	4	and Notary Public in and for the Commonwealth of
5	BY MR. ANDERSON:	5	Massachusetts, do certify that on the 30th day
6	Q. And what is the basis for that, the	6	of October, 2013, at 9:05 o'clock, the person
7	damage that you saw, the testing that you saw?	7	above-named was duly sworn to testify to the
8	MR. THOMAS: Objection.	8	truth of their knowledge, and examined, and such
9	A. We saw increased carbonyls in the	9	examination reduced to typewriting under my
10	infrared. We saw the increased oxygen in	10	direction, and is a true record of the testimony
11	SEM-EDX. We saw the lack of antioxidants, which	11	given by the witness. I further certify that I
12	would predispose the polymer to oxidation.	12	am neither attorney, related or employed by any
13	BY MR. ANDERSON:	13	of the parties to this action, and that I am not
14	Q. Did the SEM photos also support your	14	a relative or employee of any attorney employed
15	opinions in that regard?	15	by the parties hereto, or financially interested
16	A. They were the they were proof	16	in the action.
17	positive really. That just shows it's fact, it	17	In witness whereof, I have hereunto
18	happened. We can argue about how it happened,	18	set my hand this 1st day of November, 2013.
19	but it's definitely a fact that it did happen.	19	
20	MR. ANDERSON: I don't have anything	20	
21	further.	21	MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC
22	MR. THOMAS: Anybody on the phone?	22	Realtime Systems Administrator
23	MR. ESTEE: I'm sorry?	23	CSR #149108
24	MR. THOMAS: Do you have any	24	
25	questions?	25	

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		Page	310			Page 312
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 33 44	Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. It will be attached to your deposition. It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.			4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	ACKNOWLEDGMENT OF DEPONENT I,	
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 25 26 27 27 28 28 29 29 20 20 21 21 21 21 21 21 21 21 21 21 21 21 21	E R R A T A PAGE LINE CHANGE REASON:		311	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	LAWYER'S NOTES PAGE LINE	

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